

1 UNITED STATES DISTRICT COURT
2 FOR THE NORTHERN DISTRICT OF OHIO
3 EASTERN DIVISION

4 IN RE: NATIONAL)
5 PRESCRIPTION) MDL No. 2804
6 OPIATE LITIGATION)
7 Case No.
8 1:17-MD-2804
9)
10 THIS DOCUMENT RELATES) Hon. Dan A.
11 TO ALL CASES) Polster
12)

13 FRIDAY, JUNE 28, 2019

14 HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER
15 CONFIDENTIALITY REVIEW

16 - - -

17 Videotaped deposition of Ronald
18 W. Buzzeo, R.Ph., held at the offices of Williams
19 Mullen, 200 South 10th Street, Suite 1600,
20 Richmond, Virginia, commencing at 9:08 a.m.,
21 on the above date, before Carrie A. Campbell,
22 Registered Diplomat Reporter and Certified
23 Realtime Reporter.

24 - - -

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1 VIDEOGRAPHER: We are now on
2 the record.

3 My name is Devyn Mulholland.
4 I'm a videographer with Golkow
5 Litigation Services.

6 Today's date is June 28, 2019.
7 The time is 9:08 a.m.

8 This video deposition is being
9 held in Richmond, Virginia in the
10 matter of National Prescription Opiate
11 Litigation.

12 The deponent is Ronald Buzzeo.
13 Counsel, please identify
14 yourselves for the record.

15 MR. LOESER: Derek Loeser for
16 the plaintiffs.

17 MR. KAWAMOTO: Dean Kawamoto
18 for the plaintiffs.

19 MR. KO: David Ko, also on
20 behalf of the plaintiffs.

21 MS. CONROY: Jayne Conroy,
22 plaintiffs.

23 MR. LIU: Zhao Liu, O'Melveny &
24 Myers on behalf of Johnson & Johnson
25 and Janssen.

1 MS. NOWAK: Darlene Nowak,
2 Marcus & Shapira, on behalf of HBC
3 Services.

4 MR. MONTMINY: Brandan Montminy
5 on behalf of Henry Schein defendant.

6 MR. SNAPP: Erik Snapp on
7 behalf of the Purdue defendants.

8 MR. HYNES: Paul Hynes on
9 behalf of CVS, Indiana LLC and CVS RX
10 Services, Inc.

11 MS. WICHT: Jennifer Wicht on
12 behalf of Cardinal Health.

13 MS. VENTURA: Catie Ventura on
14 behalf of the Allergan defendants.

15 MR. O'CONNOR: Andrew O'Connor
16 on behalf of Mallinckrodt LLC and
17 SpecGx.

18 MS. LARUSSA: Cassandra LaRussa
19 on behalf of Mallinckrodt and SpecGx.

20 MR. DAVISON: William Davison
21 on behalf of Mallinckrodt LLC and
22 SpecGx.

23 THE WITNESS: I'm Ron Buzzeo.

24 VIDEOGRAPHER: The court
25 reporter is Carrie Campbell, who will

1 now swear in the witness.

2 RONALD W. BUZZEO, R.Ph.,
3 of lawful age, having been first duly sworn
4 to tell the truth, the whole truth and
5 nothing but the truth, deposes and says on
6 behalf of the Plaintiffs, as follows:

7 MS. BARBER: Maureen Barber
8 with Morgan Lewis for the Teva
9 defendants.

10 MS. HUGHES: Alyssa Hughes with
11 Barnes & Thornburg on behalf of
12 HD Smith.

13 MR. MARTIN: Zach Martin with
14 Fox Rothschild on behalf of
15 Prescription Supply.

16 MS. DICIURCIO: Alison
17 DiCiurcio of Covington & Burling on
18 behalf of McKesson.

19 MR. HEINEN: Greg Heinen, Foley
20 & Lardner, on behalf of Anda.

21 MR. LAVELLE: John Lavelle from
22 Morgan Lewis on behalf of Rite Aid.

23 MS. FUMERTON: Tara Fumerton
24 from Jones Day on behalf of Walmart.

25

1 EXAMINATION

2 QUESTIONS BY MR. LOESER:

3 Q. Good morning, Mr. Buzzeo.

4 A. Good morning.

5 Q. Could you please state and
6 spell your name for the record, your last
7 name?

8 A. Yeah. Ronald W. Buzzeo,
9 B-u-z-z-e-o.

10 Q. And have you ever been known by
11 any other name?

12 A. Ron, Buzz.

13 Q. And, Mr. Buzzeo, you understand
14 that you're under oath today?

15 A. Yes.

16 Q. And is there any reason why you
17 would be unable to testify truthfully and
18 accurately today?

19 A. There's no reason that I'm
20 aware of.

21 Q. Are you taking any medication
22 that would interfere with your ability to
23 answer my questions fully and truthfully?

24 A. No.

25 Q. Sir, have you been deposed

1 previously?

2 A. I believe one occasion.

3 Q. Okay. Well, I'll remind you of
4 the ground rules, and just a few of them that
5 are most important.

6 The first rule, it's important
7 that we not talk at the same time, and so if
8 I ask you a question, if you could let me
9 finish asking the question before you try and
10 answer, and I'll do the same with your
11 answers. I'll try not to interrupt you while
12 you're answering.

13 Is that okay?

14 A. (Witness nods head.)

15 Q. And when you answer a question,
16 if you could do so verbally --

17 A. Okay.

18 Q. -- so shaking your head --

19 A. I understand.

20 Q. Okay. So yes or no or an
21 explanation.

22 A. Yes.

23 Q. And if you don't understand a
24 question, please ask me to restate it and I
25 will try to do so.

1 A. I will.

2 Q. And if you do answer the
3 question, I assume that you understood the
4 question.

5 If at any time you need to take
6 a break, please let me know or let your
7 counsel know. And it might not be
8 immediately upon request, but I'll try and
9 take a break soon after you've requested one.

10 Does that sound fair to you?

11 A. That's fine.

12 Q. And if you can't hear me
13 because I'm not speaking loud enough or I'm
14 speaking too quickly, please let me know.

15 A. I will tell you.

16 Q. And this is a good little test
17 case for us because on a few occasions you've
18 nodded. I understand what you're saying, but
19 you do need to state clearly and verbally for
20 the record.

21 A. I agree.

22 I ask one thing, though, that
23 you look at me when you -- if you could when
24 you're asking the question.

25 Q. Sure, I'll try and do that.

1 A. If you try.

2 (Buzzeo Exhibit 1 marked for
3 identification.)

4 QUESTIONS BY MR. LOESER:

5 Q. Why don't we go ahead and mark
6 your deposition notice as Exhibit 1.

7 Mr. Buzzeo, you've been handed
8 what is now marked Exhibit 1, which is the
9 notice of your deposition for today.

10 Have you seen this document
11 before?

12 A. Yes.

13 Q. And when did you see it?

14 A. Yesterday.

15 Q. And, sir, have you brought any
16 materials with you today to this deposition?

17 A. No.

18 Q. Okay. I see that there's --
19 what looks like a chart or a spreadsheet
20 sitting in front of you.

21 Is that something that you
22 intend to rely on during your testimony?

23 A. Yes.

24 MR. LOESER: Okay. If we could
25 have that marked as an exhibit, I

1 would appreciate it.

2 (Buzzeo Exhibit 2 marked for
3 identification.)

4 MR. LOESER: Mark that as
5 Exhibit 2.

6 QUESTIONS BY MR. LOESER:

7 Q. Mr. Buzzeo, do you mind if I
8 take a quick look at that document?

9 MR. DAVISON: This might be
10 easier.

11 QUESTIONS BY MR. LOESER:

12 Q. And, sir, can you tell me what
13 this document is?

14 A. It's a timeline so that I could
15 be as accurate as possible if we talk about
16 certain issues and the time frame it was in.

17 Q. And who prepared this timeline?

18 A. I discussed it with one of the
19 Ropes & Gray attorney and asked him to
20 prepare it.

21 Q. And when did you do that?

22 A. Early part of this week.

23 Q. And is there anything on this
24 timeline that was put on by counsel instead
25 of by you?

1 A. This was put on after we had
2 that discussion of what I would like to see
3 on the timeline. Because as you know, I
4 wrote my report in various sections.

5 Q. Your counsel has provided us
6 the invoice that you submitted for your work
7 in this case, and I'll -- we'll mark that as
8 the next exhibit.

9 (Buzzeo Exhibit 3 marked for
10 identification.)

11 QUESTIONS BY MR. LOESER:

12 Q. Sir, you're now looking at
13 what's been marked Exhibit 3.

14 Is this the invoice that you
15 submitted to Mallinckrodt counsel --

16 A. Yes.

17 Q. -- for this matter?

18 And your hourly rate is \$450 an
19 hour; is that correct?

20 A. Correct.

21 Q. And is that the same rate for
22 all the work that you're going to do in this
23 case?

24 A. Yes.

25 Q. And so if you testify at trial,

1 for example, it would not be a different
2 rate?

3 A. No, same.

4 Q. And is this the only invoice
5 that you've submitted to counsel for
6 Mallinckrodt?

7 A. Yes.

8 Q. And did you prepare this
9 invoice?

10 A. Yes.

11 Q. You did personally?

12 A. Yes.

13 Q. And are there other invoices
14 that you intend to submit?

15 A. One for this week.

16 Q. Okay. Do you know how many
17 hours are indicated on that?

18 A. Depending on today, maybe 17,
19 18, somewhere around -- let's say
20 approximately 20 hours.

21 Q. Okay. And the amount of this
22 invoice is \$130,050; is that correct?

23 A. Yes.

24 Q. And that's for a total of
25 289 hours?

1 A. Yes.

2 Q. And according to this invoice,
3 you spent 176 hours reviewing documents; is
4 that correct?

5 A. Correct.

6 Q. And 45.5 hours drafting your
7 report?

8 A. Yes. Preparing the report.

9 Q. Preparing your report.
10 Is that different than drafting
11 the report?

12 A. To me it is because what I'll
13 usually do is when I -- if I know I'm going
14 to be preparing a report, as I review
15 documents, if I feel that I'm going to use
16 any information in that document in my
17 report, I will begin to write out a paragraph
18 or something of what I've read that I think
19 is important that I may want to put in the
20 room.

21 Q. Okay. And so do you know how
22 many hours you spent actually drafting your
23 report?

24 A. For the actual report, when I
25 was taking my notes and everything and

1 putting into it, it was 45 hours.

2 Q. And do you have copies of those
3 notes?

4 A. Yes.

5 Q. Did you bring them with you
6 today?

7 A. No.

8 Q. But you've kept copies of them?

9 A. Yes.

10 Q. And the other item on this
11 invoice, it says, "Meetings and calls with
12 Ropes & Gray attorneys," and it indicates
13 67.5 hours?

14 A. Yes.

15 Q. When did those meetings and
16 calls occur? Over what time period?

17 A. Probably starting in April.

18 Q. And how many meetings?

19 And by "meetings," does that
20 mean in-person meetings?

21 A. Yes.

22 Q. How many in-person meetings?

23 A. About eight, I'd say.

24 Q. And who were those meetings
25 with?

1 A. Counsel from Ropes & Gray.

2 Q. And can you name who was
3 present?

4 A. Yes, the two attorneys to my
5 left, Bill and Case {sic}.

6 Q. And nobody else was there?

7 A. No.

8 Q. No counsel for any other
9 defendants?

10 A. No.

11 Q. And what about the calls, how
12 many calls have you had?

13 A. I don't really recall, but I'd
14 say approximately five or six calls.

15 Q. And were those with the same
16 two counsel from Ropes & Gray?

17 A. Yes, but on one -- one call
18 there was a couple other counsels from Ropes
19 & Gray.

20 Q. And on this invoice, on review
21 of documents, 176 hours, are those -- is that
22 the review of all the documents that are
23 identified on your materials considered list?

24 A. Yes. Yes.

25 Q. Okay. There were no other

1 documents that you reviewed that's
2 included --

3 A. No other documents.

4 MR. DAVISON: Let him finish
5 his questions.

6 QUESTIONS BY MR. LOESER:

7 Q. No other documents that you
8 reviewed that are not on that list?

9 A. Correct.

10 Q. And did you meet with counsel
11 to prepare for this deposition?

12 A. Yes.

13 Q. How many times?

14 A. Maybe three times.

15 Q. And can you tell me the length
16 of each meeting?

17 A. I'd say approximately six
18 hours, six and a half hours.

19 Q. Okay. Where did those meetings
20 occur?

21 A. In Chocowinity, North Carolina,
22 and Richmond.

23 Q. And who was present at those
24 meetings?

25 A. The two counsels to my left.

1 Q. In the course of preparing your
2 report, did you meet with any employees of
3 Mallinckrodt?

4 A. No.

5 Q. Did you talk on the phone to
6 any employees of Mallinckrodt?

7 A. No.

8 Q. Sir, what company retained you
9 in this case?

10 A. Ropes & Gray.

11 Q. And they did so on behalf of
12 Mallinckrodt?

13 A. Yes.

14 Q. And I may have asked, but what
15 was the date of when you were retained?

16 A. I want to say -- again, I don't
17 really remember, but -- I don't recall the
18 exact date, but probably was in -- probably
19 March sometime. I could be off, but I would
20 say around March maybe, possibly.

21 Q. March, March of 2019?

22 A. Yes.

23 Q. And is Mallinckrodt a client of
24 yours in any other capacity than as an
25 expert?

1 A. Of mine, no.

2 Q. Has Mallinckrodt ever been a
3 client of yours in the past?

4 And by "yours" I mean you or
5 BuzzeoPDMA or...

6 A. Mine a number of years ago, and
7 I don't recall if -- currently if they are a
8 client of my old company or not.

9 Q. Okay. So let me try and
10 understand what you're saying.

11 Mallinckrodt was a client of
12 yours some number of years ago?

13 A. Way back.

14 Q. And was that while you were
15 with BuzzeoPDMA?

16 A. I don't recall whether it was
17 when I was with the Agency -- or excuse me,
18 probably when I was BuzzeoPDMA --

19 Q. Okay.

20 A. -- or Buzzeo & Associates.

21 Q. Do you recall what year that
22 was?

23 A. God, no.

24 Q. Do you recall what the nature
25 of the consulting or whatever your

1 involvement with them was?

2 A. Yes, I do.

3 Q. Can you tell me about that,
4 please?

5 A. It was to review their bulk
6 manufacturing operation.

7 Q. And what were you reviewing
8 about it?

9 A. How to do an accountability or
10 an accountability of raw material and the
11 alkaloids associated with raw material.

12 So if you have opium and you
13 process it, how much hydrocodone you're going
14 to get out of it, how much codeine, how much
15 morphine, in order to account for the
16 process.

17 Because the DEA requires if you
18 import so much opium, what are you actually
19 getting out of it, how do you account for
20 that.

21 Q. And do you recall -- you don't
22 recall the year that that occurred?

23 A. No, I don't recall. It was so
24 long ago.

25 Q. Any rough range when you think

1 it may have happened?

2 A. (Witness shakes head.)

3 Q. And did you conduct --

4 A. Excuse me. Now, you used the
5 word "client," so I had to be careful on
6 that. I don't remember whether it was when I
7 was with the Agency or when I first went out
8 on my own.

9 Q. You don't recall whether you
10 were actually retained by Mallinckrodt or
11 not, because I gather you wouldn't have been
12 retained if it was with the Agency?

13 A. No, that's right. Yes, so I
14 wouldn't have been retained, so I wanted to
15 be very clear on that.

16 But if it was still when I
17 first went out, say, in the early '90s, then
18 it would have been a client.

19 Q. And do you recall whether you
20 prepared a report about that engagement?

21 A. I don't recall. I would
22 assume, but I don't recall.

23 Q. Was that your normal practice
24 when you were engaged to review a company's
25 procedures or systems?

1 A. What -- clarify when you say
2 "normal practice."

3 Q. Was it a normal practice of
4 yours to prepare a report for your consulting
5 clients?

6 A. It depended on the client, it
7 depended why I was there, whether a report
8 was prepared or not. So if it was a training
9 session, there'd be no report. If it was a
10 review and they requested a report, there'd
11 be a review. It could have been verbal.

12 Q. And do you have any files that
13 would allow you to check and learn more
14 details about this engagement?

15 A. No.

16 Q. Would --

17 A. Go ahead.

18 Q. Do you believe BuzzeoPDMA would
19 have those files?

20 MR. DAVISON: Objection.

21 THE WITNESS: The practice was
22 not to -- when I was there -- I don't
23 know what the practice is today -- is
24 once you do a report, they would --
25 there really is no need to keep that,

1 those reports.

2 So I don't know if they have
3 them or they don't have them. I know
4 I don't have any. I didn't keep
5 anything.

6 QUESTIONS BY MR. LOESER:

7 Q. Okay. Now, you've described
8 one prior potential engagement with
9 Mallinckrodt.

10 Can you recall any others prior
11 to this one?

12 A. I don't recall any others. And
13 the only reason that sticks in my mind is
14 because it's a bulk manufacturer, and the
15 process is just intriguing.

16 Q. And how about any -- just any
17 contact with Mallinckrodt? Did you
18 communicate with Mallinckrodt at any time, or
19 counsel for Mallinckrodt, prior to your
20 engagement in this case?

21 MR. DAVISON: Objection.

22 THE WITNESS: The only contact
23 was on a call when they were
24 considering whether -- when Ropes &
25 Gray was considering -- that was it.

1 It was just whether I should be hired
2 or not hired.

3 QUESTIONS BY MR. LOESER:

4 Q. And when did that occur?

5 A. Prior to my being retained.

6 Because we didn't discuss business. It was
7 more of a, you know, who are you, what do you
8 do, things like that.

9 Q. And this was before
10 Mallinckrodt actually retained you?

11 A. Excuse me?

12 Q. This was before you were
13 actually retained?

14 A. Yes.

15 Q. Have you been retained to serve
16 as an expert by any other defendant in this
17 case?

18 A. No.

19 Q. Have you communicated with any
20 of the other defendants or their counsel
21 regarding this case?

22 A. No.

23 Q. Now, your opinions in this
24 case, they are on behalf of Mallinckrodt?

25 A. Yes.

1 Q. And are your opinions intended
2 to be on behalf of any other defendant?

3 A. I was retained to look at
4 Mallinckrodt's program and prepare a report
5 on Mallinckrodt's compliance with the
6 regulations. I don't intend to share with
7 anybody else, and so I would say no.

8 Q. And so you are, in fact, not
9 providing an opinion on behalf of any other
10 defendant; is that right?

11 A. I'm not.

12 Q. As you sit here today, do you
13 anticipate doing significant additional work
14 in this case before trial?

15 A. To prepare for trial, I would
16 say yes.

17 Q. And describe for me what you
18 think you will be doing.

19 A. Reviewing the report, my
20 report, maybe looking at depositions from the
21 plaintiffs' side, any reports from the
22 plaintiffs' side, documents such as that.

23 Q. Okay. And other than the items
24 listed in your materials considered, have you
25 reviewed any of those reports or other

1 matters that you think you might review to
2 prepare for trial?

3 A. The only thing I've reviewed is
4 what's in my report -- what I list in my
5 report.

6 Q. Okay. So you're saying that
7 you may review additional materials prior to
8 trial?

9 MR. DAVISON: Objection.

10 THE WITNESS: I think I -- oh,
11 I'm sorry.

12 MR. DAVISON: Go ahead.

13 THE WITNESS: I got to stop
14 that.

15 I would leave the option open
16 that maybe there's some additional
17 records I should -- I feel I should
18 look at.

19 QUESTIONS BY MR. LOESER:

20 Q. Did anyone assist you with your
21 work in preparing your report in this case?

22 A. When I -- I prepared the
23 report, the words of my report. The
24 assistance provided was putting it in -- you
25 know, putting it in final format.

1 Q. Okay. And so is that
2 assistance that was provided by counsel for
3 Mallinckrodt?

4 A. Yeah, Ropes & Gray.

5 Q. And tell me what you mean by
6 "putting it into final format."

7 A. I had a draft report, had to be
8 finalized. They were good enough to type it
9 out and put in the footnotes for me because I
10 really don't know how to put footnotes in the
11 report.

12 Q. And did they write parts of the
13 report?

14 A. Not at all.

15 Q. Okay. So you wrote every word
16 that's in that report?

17 A. Yes.

18 Q. And you wrote the footnotes as
19 well?

20 A. I pulled -- when I used -- in
21 writing my report, a section, I pulled it
22 from a document or deposition, something like
23 that, I would list what I took it from, and
24 they would put the footnote in for me.

25 Q. Okay. What was the condition

1 of the draft when you provided it to counsel
2 to put into final format?

3 MR. DAVISON: Objection.

4 THE WITNESS: What I do when I
5 write a report is I will use a
6 computer and prepare the report, and
7 that will be a draft. And then maybe
8 a day or so later I'll go back to it,
9 and I'll change something and save it.
10 So I'm working always on the same
11 document and saving it.

12 I may read another document
13 that I have, a deposition, pull
14 something out of that, you know, put
15 them in my own words again. Take that
16 same draft I had, put the changes in
17 there and save that.

18 So that -- that's the condition
19 of my draft.

20 So when I prepared the final --
21 and Ropes & Gray, like I said, was
22 good enough to add the footnotes and
23 prepare this document.

24 QUESTIONS BY MR. LOESER:

25 Q. Okay. And so did you -- I want

1 to make sure I understand what assistance
2 counsel provided for this.

3 Did you draft the table of
4 contents in your report?

5 A. Yes.

6 Q. Okay. So if I flip through
7 this report, did you organize the report in
8 the order that it's in?

9 A. Yes.

10 Q. And did you write the headings
11 in the report?

12 A. When you say "the headings,"
13 what are you referring to?

14 Q. The different sections that are
15 in bold.

16 A. Yes.

17 Q. Okay. And did you write the
18 summary of your opinions at the beginning of
19 your report?

20 A. Excuse me?

21 Q. Did you write the summary of
22 your opinions at the beginning of your
23 report?

24 A. Yes. After I -- as I mentioned
25 earlier, I was retained to look at

1 Mallinckrodt's program, to render a decision
2 on that, and that's the way I wrote my
3 report. And the summary of findings are --
4 as I said, everything in here is my words.

5 Q. And you mentioned assistance
6 from Ropes & Gray.

7 Did you have anyone else
8 working with you directly in preparing your
9 report?

10 A. No.

11 Q. So you worked by yourself?

12 A. Yes.

13 Q. Sir, can you tell me what you
14 think this case is about?

15 MR. DAVISON: Objection.

16 THE WITNESS: Plaintiffs are --
17 filed a civil case against the
18 industry purporting that the industry
19 has led to the diversion problem in
20 the United States, abuse problem.

21 When we all -- when, you
22 know -- so that's it.

23 Okay. Go ahead. Back to your
24 question.

25

1 QUESTIONS BY MR. LOESER:

2 Q. Were you finished answering,
3 sir?

4 A. Yes.

5 Q. And is that an explanation that
6 you came up with on your own after reviewing
7 materials, or was that provided to you by
8 somebody else?

9 A. No, that's what I read in the
10 news media or heard on TV or understanding.

11 Q. And you used the expression
12 "diversion problem."

13 Can you please explain to me --

14 A. Well, I should have used the
15 word "abuse problems" in the United States,
16 that there's some allegations that
17 pharmaceutical products are being abused.

18 We also know that heroin and
19 fentanyl are major problems in the United
20 States that are causing a lot of deaths. And
21 that's what I was referring to, both the
22 licit and illicit.

23 Q. So you're equating abuse
24 problem with diversion problem?

25 MR. DAVISON: Objection.

1 THE WITNESS: Well, it's like
2 heroin is diverted, or it comes from a
3 diverted product, or fentanyl. We
4 know a lot of it's coming in from
5 overseas. Is it being diverted from a
6 pharmaceutical company over in China
7 or is it clandestinely manufactured.

8 So when I use the term
9 "diversion," it's a very broad term.
10 You could have diversion of trucks or
11 cars or liquor or anything else.

12 QUESTIONS BY MR. LOESER:

13 Q. And do you use the term also to
14 mean diversion of prescription opioids?

15 A. Probably the word "diversion"
16 was a poor choice. I probably should have
17 used the word "abuse."

18 But if you have leakage from a
19 legitimate distribution chain, that would be
20 considered diversion.

21 Q. And are there any other kinds
22 of diversion that you think contributed to
23 what you earlier referred to as the diversion
24 problem?

25 A. Clarify that question.

1 Q. Would you say prescription
2 drugs are also diverted?

3 A. You wouldn't -- yeah, there's
4 some diversion of prescription product.

5 The question is, where is it
6 being diverted, how large of a problem it is,
7 is it causing a lot of deaths.

8 So it's all of those issues.

9 Q. And, sir, what's your
10 understanding of the plaintiffs' claims
11 against Mallinckrodt specifically?

12 A. That some of their product was
13 abused on the street, which when I looked at
14 their program, and based upon my 50-something
15 years of experience, I think Mallinckrodt
16 has -- not that I think -- I know
17 Mallinckrodt has a very compliant program.

18 Q. Right.

19 But in terms of what the
20 plaintiffs' claims are against Mallinckrodt,
21 can you provide any other detail on what you
22 think those claims are about?

23 A. Well, the claim is, as I
24 understand it, is that their product is being
25 abused on the street, which I haven't found

1 evidence of it.

2 I think that's one of the
3 issues when it comes to a generic product and
4 not a branded product, is you really don't
5 know what products are being diverted on the
6 street.

7 So -- and then I still think
8 that the vast majority of the abuse on the
9 street is from heroin and fentanyl.

10 Q. And, sir, what have you
11 reviewed to develop your understanding of the
12 plaintiffs' claims against Mallinckrodt?

13 A. Just what I've heard on the
14 news and the newspapers, things like that.

15 Q. Did you read the complaint in
16 this case?

17 A. Just read quickly through it.
18 I didn't really go into very much detail. I
19 skimmed it.

20 Q. Do you recall when you did
21 that?

22 A. A few months ago.

23 Q. Do you recall who the plaintiff
24 was in the complaint that you skimmed?

25 A. States, counties, probably some

1 cities.

2 Q. And, sir, did you read or skim
3 one complaint or many complaints?

4 A. I looked at many documents from
5 the -- from the courts.

6 Q. But of those documents, do you
7 know how many were actual complaints filed in
8 this case?

9 A. No. No.

10 Q. Mr. Buzzeo, do you believe
11 there's an opioid epidemic in this country?

12 MR. DAVISON: Objection.

13 THE WITNESS: Are you talking
14 about --

15 MR. DAVISON: Go ahead.

16 THE WITNESS: Are you talking
17 about licit or illicit?

18 QUESTIONS BY MR. LOESER:

19 Q. How would you define the term
20 "opioid epidemic"?

21 A. Licit or illicit?

22 Q. Do you define it as including
23 both of those things or just one or the
24 other?

25 A. Well, "epidemic" is a broad

1 term. You know, what's causing the most
2 deaths in the United States. So is that the
3 epidemic?

4 If it's opioid -- legitimate
5 opioids, you know, is it actually -- is there
6 large quantities? Is there's not large
7 quantities that's causing injuries? What's
8 the injuries? So "epidemic" to me is a very
9 broad term.

10 If you're talking about deaths,
11 my opinion would be fentanyl and heroin.

12 Q. Okay. So I'm trying to
13 understand whether you believe there is, in
14 fact, an opioid epidemic.

15 However you define that term,
16 do you believe there's an opioid epidemic in
17 this country?

18 MR. DAVISON: Objection.

19 THE WITNESS: I think there's a
20 illicit epidemic in the United States,
21 and I think some pharmaceutical
22 products, yes, are being abused.

23 There's probably a certain
24 percentage of the population that will
25 abuse anything.

1 You do have pain clinics out
2 there. You had the Internet
3 pharmacies in the past. You had
4 pharmacies dispensing excessive
5 quantities. You had doctors
6 prescribing. You had doctors hired to
7 prescribe, and you had people owning
8 pharmacies so they could divert.
9 Yeah, you have that issue.

10 QUESTIONS BY MR. LOESER:

11 Q. Sir, have you ever read any
12 books or articles that use the term "opioid
13 epidemic"?

14 A. Just what I've seen in the
15 paper and the -- some of the stuff I looked
16 at.

17 Q. And when you've seen reference
18 to the opioid epidemic, have you thought to
19 yourself, well, there really isn't an opioid
20 epidemic?

21 A. I've never said there's not
22 really an epidemic. I've said there's an
23 abuse of controlled substances, both licit
24 and illicit.

25 And if you look at the number

1 of deaths, I firmly believe that most of them
2 are caused by heroin and fentanyl. If you
3 look at the abuse of legitimate
4 pharmaceuticals, yes, there is some abuse.

5 But, like I said, I was hired
6 mainly and retained mainly to look at
7 Mallinckrodt's program and to see whether
8 they were compliant with the regulations, not
9 to look down at a pharmacy or some other type
10 of registrant.

11 As you know, there's a total
12 distribution chain, an entire distribution
13 chain.

14 Q. Mr. Buzzeo, you mentioned
15 before that you thought there were more
16 deaths.

17 Do you recall saying that?

18 A. (Witness nods head.)

19 Q. How do you know there are more
20 deaths?

21 MR. DAVISON: Objection.

22 THE WITNESS: I've seen -- I'd
23 heard that on a TV show, that the vast
24 majority of the deaths caused in the
25 United States was caused by heroin and

1 fentanyl.

2 And there was a discussion the
3 other day on the radio I was listening
4 to when I was driving that talked --
5 and I don't have all the details,
6 something CDC is even questioning now,
7 whether they were overstringent in
8 some of their correspondence and it's
9 having a negative impact on legitimate
10 patients trying to get pain.

11 I'm not an expert in that area.
12 There are experts in that area. I'm
13 just repeating what I've heard.

14 QUESTIONS BY MR. LOESER:

15 Q. Okay. And so --

16 A. I heard yesterday.

17 Q. -- this conversation started
18 with me asking you if you're aware of the
19 opioid epidemic, and you provided some
20 information now about more deaths.

21 And the source for your
22 testimony was something that you saw on
23 television?

24 MR. DAVISON: Objection.

25 THE WITNESS: News media.

1 Let's say the news media.

2 QUESTIONS BY MR. LOESER:

3 Q. Okay. Do you recall what news
4 media?

5 A. Oh, I don't remember, the radio
6 or the TV -- some TV show.

7 But, again, when we talk about
8 an opioid epidemic, we need to clarify
9 whether we're talking about legitimate or
10 illicit.

11 Q. And you mentioned that you --
12 that the vast majority of opioids being
13 abused are illicit opioids.

14 How do you know that?

15 A. Excuse me?

16 Q. You testified a few minutes ago
17 that the vast majority of opioids being
18 abused are illicit opioids.

19 A. Like I said, what I've seen and
20 what I've read.

21 Q. Okay. So your basis for that
22 statement was things you've seen on
23 television?

24 A. Television, news media,
25 articles on the Internet. But again, I'm not

1 saying I'm an expert in that area, and there
2 are experts out there that -- and even CDC,
3 as I was telling you about yesterday, that
4 should be talked to. Those are the people
5 you should focus on.

6 Q. And, sir, what is a legitimate
7 opioid? You used that expression.

8 A. A legitimate controlled
9 substance is something that's made by --
10 either a raw material is imported or it's
11 made in the United States and flows through
12 the distribution chain.

13 And it's controlled by quota,
14 by DEA. If you're talking about opioids, the
15 DEA controls, and FDA, the amount that can be
16 manufactured.

17 Q. And what do you mean by licit
18 versus illicit?

19 A. Illicit is something that's
20 clandestinely manufactured. Heroin-like is
21 clandestine. Cocaine is clandestine, even
22 though it's legitimately manufactured
23 cocaine. Fentanyl, there's illicit, which
24 comes out -- it's smuggled into the United
25 States, versus what's manufactured in the

1 United States.

2 Q. And is a prescription pill, if
3 diverted, an illicit opioid?

4 A. No.

5 MR. DAVISON: Objection.

6 QUESTIONS BY MR. LOESER:

7 Q. How would you characterize a
8 prescription pill that is diverted then?

9 A. It's for a nonmedical use.

10 Q. And do you know, sir, what
11 portion of the opioids that are abused in
12 this country fall into that category as
13 opposed to the illicit category?

14 A. I don't know.

15 Q. You've never tried to study
16 that?

17 A. Well, years ago, you know, I
18 would look at the DAWN data.

19 Q. I'm sorry, you'd look at?

20 A. DAWN data, Drug Abuse Warning
21 Network. It came out of NIDR or FDA.

22 MR. DAVISON: And, Ron, if
23 you're going into things that you did
24 at DEA that would go into confidential
25 investigations or anything, I just

1 want to remind you of the Touhy letter
2 that you received on that. I'm not
3 sure what time period you're talking
4 about.

5 THE WITNESS: Yeah, thank you.

6 I'm talking about when I was --
7 when I was working full-time.

8 QUESTIONS BY MR. LOESER:

9 Q. I'm sorry, did you complete
10 your answer?

11 A. When I was working full-time.
12 I didn't refer -- I wasn't referring to the
13 Agency time.

14 Q. Do you agree that opioid abuse
15 and diversion has become a serious public
16 health problem?

17 A. Opioids have become a serious
18 health problem, both the illicit and to some
19 extent licit.

20 But the illicit, I think
21 since -- from what my understanding is, the
22 amount of prescriptions are decreasing. And
23 that's what the program I was listening to
24 the other day was talking about: Has there
25 been a switch where legitimate patients are

1 not getting their medication.

2 So there's always a balance, as
3 I've looked over my whole career, between
4 meeting a legitimate medical need but not
5 feeding the illicit market through bad
6 pharmacies and bad physicians.

7 Q. And, sir, have you met patients
8 who are not able to obtain opioids for
9 legitimate medical purposes?

10 A. Not currently, no.

11 Q. Have you ever met such a
12 person?

13 A. Yes. I was on a number of
14 panels where we would put seminars on for
15 physicians, nurses, pharmacists, and on that
16 panel discuss -- I would talk about the
17 regulatory requirements.

18 There was a doctor in there who
19 talked about pain management. There were
20 state people that would talk about what the
21 state does. There were people in there that
22 would talk about patients, illicit patients,
23 trying to get medical -- medicine outside of
24 legitimate distribution chain. So that was
25 the type of panel.

1 And so I would hear -- and we
2 also would have a patient, a former addict, a
3 patient that was having problems getting --
4 they would provide, and it was also CE
5 credits issued by the state. So the state
6 actually put it on, working with the
7 pharmaceutical industry, to provide education
8 to physicians, pharmacists, on how they
9 should handle controlled substances, how they
10 should handle these drug-seeking patient. So
11 these were educational seminars to address
12 certain issues that we're talking about.

13 Q. And when did those occur?

14 A. I was on those -- and don't
15 hold me to these dates, but I would say -- it
16 was after I retired, so it was probably
17 starting in the '90s.

18 Q. Okay. And when was the last
19 one you recall?

20 A. I don't recall.

21 Q. Have there been any of those
22 panels --

23 A. I don't recall.

24 Q. -- since the '90s?

25 A. I don't recall if they carried

1 on.

2 Q. And so, sir, your understanding
3 of a legitimate opioid is one that's used for
4 a medical purpose?

5 A. No, the legitimate controlled
6 substance is one that's manufactured in the
7 United States by a pharmaceutical company and
8 then moves down to the distribution chain to
9 the practitioner level.

10 Q. That's the definition of
11 legitimate?

12 A. That's legitimate.

13 Q. Mr. Buzzeo, do you believe that
14 diversion of prescription opioids contributed
15 to the opioid crisis in this country?

16 MR. DAVISON: Objection.

17 THE WITNESS: Contributed --
18 repeat your question.

19 QUESTIONS BY MR. LOESER:

20 Q. Do you believe that the
21 diversion of prescription opioids contributed
22 to the opioid crisis in this country?

23 MR. DAVISON: Objection.

24 THE WITNESS: No, I think it's
25 a combination of some -- you know, of

1 abuse of pharmaceutical products, but
2 then you also have the large market of
3 illicit substances, which is heroin
4 and fentanyl today, that also led to
5 that.

6 But -- and beyond that, it's
7 probably a much larger issue than --
8 and I'm not an expert that I can
9 discuss about society and issues such
10 as that. So I think it's -- it's a
11 much larger issue that you would have
12 to talk to other experts on. That's
13 my firm belief.

14 QUESTIONS BY MR. LOESER:

15 Q. And, sir, do you believe that
16 any opioid manufacturers contributed to the
17 opioid crisis by not having in place adequate
18 controls to prevent diversion?

19 MR. DAVISON: Objection.

20 THE WITNESS: Like I said
21 earlier, I was retained by Ropes &
22 Gray to look at the Mallinckrodt
23 program. And I can speak to the
24 Mallinckrodt program; I haven't
25 reviewed any others.

1 And as far as I'm concerned,
2 based upon my 50-plus years of
3 experience, Mallinckrodt has -- to me
4 has a compliant program.

5 QUESTIONS BY MR. LOESER:

6 Q. And, sir, I'm asking you about
7 your 50-plus years of experience, and so I'll
8 ask again.

9 Do you believe that any opioid
10 manufacturers contributed to the opioid
11 crisis by not having in place adequate
12 controls to prevent diversion?

13 MR. DAVISON: Objection.

14 THE WITNESS: I can't answer
15 that question. You could give me a
16 name or something, but I can't answer
17 that question. I don't know. I'm not
18 aware of -- I should put it this way,
19 I'm not aware of any.

20 QUESTIONS BY MR. LOESER:

21 Q. Okay. In your 50-plus years of
22 guiding and providing consulting services to
23 opioid manufacturers, you're not aware of any
24 manufacturers that contributed to the problem
25 by not having in place adequate suspicious

1 order monitoring systems?

2 MR. DAVISON: Objection.

3 THE WITNESS: If you're asking
4 me -- I can't talk about anything with
5 the Agency, so that period of time we
6 have to take out of there.

7 If you're -- the people I dealt
8 with -- and I have -- I can't -- I
9 can't recall. Like I said, I focused
10 on the Mallinckrodt program, and only
11 the Mallinckrodt program, at this
12 time.

13 QUESTIONS BY MR. LOESER:

14 Q. Mr. Buzzeo, do you believe that
15 any opioid distributors contributed to the
16 opioid crisis by not having in place adequate
17 controls to prevent diversion?

18 MR. DAVISON: Objection.

19 THE WITNESS: Again, I --

20 MS. DICIURCIO: Objection.

21 COURT REPORTER: Who on the
22 phone objected?

23 MS. DICIURCIO: That was Alison
24 DiCiurcio from Covington.

25 THE WITNESS: I was retained --

1 repeat your question.

2 MR. LOESER: Could you read the
3 question back, please?

4 (Court Reporter read back
5 question.)

6 THE WITNESS: As I said
7 earlier, I don't recall, but I was
8 hired by Ropes & Gray to look at the
9 Mallinckrodt program. I'm not here to
10 talk about other individuals, the
11 other registrants, that I may not be
12 aware of.

13 MR. LOESER: Could you read the
14 question back again, please?

15 QUESTIONS BY MR. LOESER:

16 Q. Sir, Mr. Buzzeo, I'm going to
17 ask you the question again, and if you could
18 please answer it, I'd appreciate it.

19 (Court Reporter read back
20 question.)

21 MR. DAVISON: Objection.

22 MS. DICIURCIO: Objection.

23 THE WITNESS: It's too broad of
24 a question. I'm not aware of any. I
25 know there's been some action years

1 ago by DEA on some, but I'm not aware
2 of any.

3 QUESTIONS BY MR. LOESER:

4 Q. Sir, when you say "there's been
5 some action by the DEA," what are you
6 referring to?

7 A. Some of the -- I'm assuming,
8 I'm just guessing, there's been some action
9 by them. I'm not aware of any.

10 Q. You're not aware of any, but
11 you recall some action by the DEA?

12 A. Well, there's been a lot of
13 action. Whether they've gone down that road
14 or not, I'm really not aware.

15 Again, I keep wanting to
16 repeat, I was retained to look at the
17 Mallinckrodt program and to determine whether
18 they met the compliance requirements.

19 Q. Mr. Buzzeo, do you believe that
20 any chain pharmacies contributed to the
21 opioid crisis by not having in place adequate
22 controls to prevent diversion?

23 MR. DAVISON: Objection.

24 THE WITNESS: I'm not aware of
25 any.

1 QUESTIONS BY MR. LOESER:

2 Q. I'm sorry?

3 A. I'm not aware of any.

4 Q. Mr. Buzzeo, through your years
5 of providing guidance to DEA registrants, did
6 you become familiar with the concept of pill
7 migration?

8 A. Pill migration? I've never
9 heard of that term.

10 Q. Have you ever heard the term
11 "the Oxy Express"?

12 A. Give me that again.

13 Q. "Oxy Express."

14 A. I assume you're referring, when
15 you say "oxy," oxycodone?

16 Q. Correct.

17 A. No.

18 Q. How about The Blue Highway?

19 A. The what?

20 Q. The Blue Highway?

21 A. The Blue Highway, we call it Ts
22 and Bs, I think it was. And I forgot what
23 those two -- the Ts and Bs talked to. But I
24 think that may have been the same thing.

25 Q. And when you say "we" refer to,

1 who are you speaking of?

2 A. When I was -- when I was with
3 the Agency. That's as much as I'll say about
4 it.

5 Q. Are you familiar with the DEA's
6 distributor initiative program?

7 A. What I've read about it.

8 Q. And what do you mean, what you
9 read about it?

10 A. It was a program where DEA met
11 with the distributors to discuss certain
12 issues, and I believe it's also in the
13 letters that the Agency put out in '06 and
14 '07.

15 Q. And what's your recollection of
16 when the Distributor Initiative Program
17 started?

18 A. As I recall, I think it was
19 around '06, '05, '06, that period of time may
20 have been right before the first letter came
21 out or after the first letter.

22 Q. And when you refer to "first
23 letter," what are you speaking to?

24 A. The letters that Joe Rannazzisi
25 from the Agency, when he was with the Agency,

1 put out to the industry, to the distributors
2 first and then manufacturers.

3 Q. And what was the purpose of the
4 Distributor Initiative Program?

5 MR. DAVISON: Objection.

6 THE WITNESS: The purpose of
7 the program, as I recall, was to
8 advise the distributors, and I wasn't
9 in any of these meetings so I can --
10 just to advise the distributors or
11 have a discussion on the requirements,
12 what they expect from the industry.

13 QUESTIONS BY MR. LOESER:

14 Q. And do you recall why the
15 Distributor Initiative Program was started?

16 MR. DAVISON: Objection.

17 THE WITNESS: No, but I do
18 recall that it was a sea change to the
19 industry. You know, they had been
20 following certain processes and
21 procedures which was accepted by the
22 Agency, and you even have -- there's
23 even some depositions where the Agency
24 says, yes, this was acceptable.

25 And then when the letters came

1 out, it caused a sea change in what
2 DEA expected the industry to do.

3 QUESTIONS BY MR. LOESER:

4 Q. And do you recall if there was
5 a crisis or something related to opioids that
6 the DEA was trying to confront through the
7 Distributor Initiative Program?

8 MR. DAVISON: Objection.

9 THE WITNESS: DEA was
10 addressing an issue, and they were
11 talking about, I believe, pharmacy
12 diversion and practitioner diversion
13 where the pharmacists and some
14 pharmacies and some physicians were
15 involved in diverting controlled
16 substances for nonmedical need.

17 QUESTIONS BY MR. LOESER:

18 Q. So your understanding of the
19 issue that DEA was addressing was diversion
20 by pharmacies and practitioners?

21 MR. DAVISON: Objection.

22 THE WITNESS: I was not with
23 the Agency at the time, but as I
24 recall, they were addressing the
25 large-scale diversion by physicians

1 and pharmacists, some physicians and
2 some pharmacists, into the illicit
3 market for -- they were prescribing
4 and dispensing for nonmedical needs.

5 QUESTIONS BY MR. LOESER:

6 Q. And why was the DEA meeting
7 with distributors about that?

8 MR. DAVISON: Objection.

9 THE WITNESS: Well, as I
10 mentioned earlier, the distribution
11 chain starts here and ends up down
12 here.

13 QUESTIONS BY MR. LOESER:

14 Q. Can you explain your answer
15 further, please?

16 A. Yeah. It goes from
17 manufacturer to the distributor to the
18 practitioner level, which is hospitals,
19 physicians, pharmacists.

20 Q. And so, sir, why was the DEA
21 meeting with distributors about diversion by
22 practitioners and pharmacies?

23 MR. DAVISON: Objection.

24 THE WITNESS: I don't know. I
25 don't recall the reason why, or maybe

1 I never remembered it, but I would
2 assume -- I don't want to assume, but
3 maybe ask for their assistance, maybe
4 make them aware of the issues.

5 QUESTIONS BY MR. LOESER:

6 Q. And, sir, did the Distributor
7 Initiative Program impact the guidance you
8 gave to your DEA registrant clients?

9 A. Personally or when I was with
10 the company?

11 Q. Personally.

12 A. Personally?

13 Q. Well, let me -- let me ask you:
14 At the time that you became aware of the
15 Distributor Initiative Program, did it impact
16 the guidance that you gave to your DEA
17 registrant clients?

18 A. Well, what -- when we worked
19 with clients, it was always to, you know,
20 discuss the regulatory requirements with
21 them, ensure that -- or recommend maybe some
22 enhancements to a program, maybe recommend
23 some things that were over and above the
24 regulations based upon our industry
25 experience. So that's what we're working

1 with the industry.

2 When DEA made the sea change,
3 which was a major change -- because you've
4 got to understand, since the '70s up until
5 the first letter went out, the issue -- and
6 DEA accepted a certain process. They came
7 out with the letter and made a sea change.

8 So I was working with them to
9 say, you know -- or they contacted us to
10 explain some sense of what DEA meant by those
11 letters, that they -- you know, it's
12 suspicious order reporting, excessive
13 reports you don't have to provide any more.
14 That's my understanding of it.

15 Q. So your answer to my question
16 is, yes, the DEA Distributor Initiative
17 Program did impact the guidance you gave your
18 clients?

19 MR. DAVISON: Objection.

20 THE WITNESS: Enhanced the
21 recommendation to go from an excessive
22 report to where all you do is give us
23 what's suspicious, which industry was
24 doing in most cases anyway, that they
25 would -- they would tell the DEA when

1 they had a suspicious order, but they
2 were also sending in these vast --
3 these excessive order reports.

4 QUESTIONS BY MR. LOESER:

5 Q. And so again, your answer is,
6 yes, the DEA Distributor Initiative Program
7 did impact the guidance that you gave to your
8 clients?

9 MR. DAVISON: Objection.

10 THE WITNESS: Depends how you
11 use the word "impact." It depends how
12 you use the word "guidance."

13 But, yes, we did work with the
14 industry to ensure that they
15 understood what those letters were
16 saying.

17 QUESTIONS BY MR. LOESER:

18 Q. Sir, what does "impact" mean to
19 you?

20 A. Does it impact a program? Does
21 it change a program? Does it enhance a
22 program? Does it go beyond the program?

23 Because even with Mallinckrodt,
24 as we'll probably get into it, there's things
25 that they did way beyond regulatory

1 requirements. And so that -- you know, those
2 are some things that could impact the
3 program.

4 Q. So using the explanation you
5 just gave, do you agree that the Distributor
6 Initiative Program impacted the guidance that
7 you gave your clients?

8 MR. DAVISON: Objection. Asked
9 and answered.

10 THE WITNESS: I've answered
11 that.

12 QUESTIONS BY MR. LOESER:

13 Q. You have not, so I'll ask
14 again.

15 Did the Distributor Initiative
16 Program impact the guidance you gave your
17 clients?

18 MR. DAVISON: Objection. Asked
19 and answered. Argumentative.

20 THE WITNESS: We would take the
21 letters, as we did, and we would sit
22 down with the companies and have a
23 discussion to make sure that we were
24 all on the same page of what the
25 intention was of DEA. Because it

1 was -- besides those letters, there's
2 been very little, if any, guidance.

3 QUESTIONS BY MR. LOESER:

4 Q. Sir --

5 A. And even DEA has admitted that.

6 So what we were trying to do
7 was make sure we were all on the same page.

8 Q. Sir, can you answer the
9 question, yes or no: Did the Distributor
10 Initiative Program impact the guidance you
11 gave your clients?

12 MR. DAVISON: Objection.

13 THE WITNESS: As I said
14 earlier, it was a sea change to the
15 industry.

16 QUESTIONS BY MR. LOESER:

17 Q. So your answer is yes?

18 MR. DAVISON: Objection.

19 THE WITNESS: There was a sea
20 change to the industry.

21 QUESTIONS BY MR. LOESER:

22 Q. And did that sea change impact
23 the guidance that you gave to your clients?

24 MR. DAVISON: Objection.

25 THE WITNESS: We work with the

1 industry on what the regulatory
2 requirements are.

3 When you look at the regulatory
4 requirements, if we're talking about
5 1301.74(b), it talks about suspicious
6 orders and reporting suspicious
7 orders. The industry practice and
8 accepted by DEA was to report
9 excessive orders -- excessive orders
10 on a monthly or quarterly basis.

11 When the letters came out, it
12 said, stop that, so that had an impact
13 on the industry. And then it -- and
14 so it did have an impact.

15 QUESTIONS BY MR. LOESER:

16 Q. Mr. Buzzeo, you provided
17 consulting services to a number of defendants
18 in this case; is that correct?

19 A. What period of time are we
20 talking about?

21 Q. Through your entire career
22 after leaving the DEA.

23 A. Oh, I don't recall all the
24 clients, but we've given consulting services
25 and provided consulting service to a number

1 of DEA registrants from the entire
2 distribution chain: the importers,
3 exporters, both manufacturers --
4 manufacturers, distributors, pharmacies, some
5 physician groups and chain pharmacies.

6 Q. And the DEA registrants for
7 which you provided guidance include some of
8 the defendants that are in this case,
9 correct?

10 A. May. I don't -- I don't
11 recall.

12 Q. Did you ask any of the other
13 defendants in this case whether they were
14 okay with you serving as an expert for
15 Mallinckrodt?

16 A. I had no discussions with any
17 of them.

18 Q. Do you know if anyone asked on
19 your behalf?

20 MR. DAVISON: Objection.

21 THE WITNESS: I don't know.

22 QUESTIONS BY MR. LOESER:

23 Q. Did you discuss with anyone,
24 other than counsel for Mallinckrodt, whether
25 you should serve as an expert in this case?

1 A. The only discussions I had was
2 with Ropes & Gray.

3 Q. And what was your initial
4 assignment in this case?

5 A. To evaluate Mallinckrodt's
6 compliance with the regulations.

7 Q. And has that assignment changed
8 at all since you were first retained?

9 A. No.

10 Q. And are there any restrictions
11 that were provided to you on what opinions
12 you can offer?

13 A. No restrictions.

14 Q. Any restrictions on parties or
15 entities that you could refer to in your
16 report?

17 A. No restrictions.

18 Q. Sir, did you review any
19 documents to prepare for your deposition
20 today?

21 A. Excuse me again.

22 Q. Did you review any documents to
23 prepare for your deposition today?

24 A. My report.

25 You mean yesterday or what time

1 period? Let's go back to time period

2 because --

3 Q. In the time period for the
4 preparation --

5 A. Okay.

6 Q. -- for your deposition.

7 A. Yes, my report. Some other
8 depositions I looked at just to refresh my
9 memory. Some reports.

10 Q. Do you recall what other
11 depositions you looked at?

12 A. Whitehall, McCann, Keller I've
13 looked at, Rafalski.

14 Q. And that was for -- preparing
15 for your deposition?

16 A. Well, it was for the review
17 leading up to the report and the deposition.

18 Q. Okay.

19 A. But for the deposition, it was
20 mainly my report.

21 Q. I'll go ahead and mark your
22 report as an exhibit.

23 (Buzzee Exhibit 4 marked for
24 identification.)

25

1 QUESTIONS BY MR. LOESER:

2 Q. And I believe -- is that
3 Exhibit 4 that you're looking at there?

4 A. 4.

5 Q. And Exhibit 4 is the report
6 that you prepared in this case?

7 A. Yes.

8 Q. And that's the copy that you
9 brought with you today?

10 A. It was a copy that legal
11 provided me today.

12 Q. All right. And it appears to
13 be your actual report?

14 A. Yes.

15 Q. And Exhibit 3 to your -- or
16 exhibit -- your report has three exhibits; is
17 that correct?

18 A. Yes.

19 Q. A through C?

20 A. Yes.

21 Q. And Exhibit A is your CV?

22 A. Yes.

23 Q. And, sir, if you can look at
24 your CV for a moment.

25 A. Yes.

1 Q. Did you prepare your own CV?

2 A. Yes.

3 Q. And is it -- did you review it
4 to make sure it was accurate?

5 A. Yes.

6 Q. And do you have other versions
7 of your CV that you use for purposes other
8 than litigation?

9 A. Different formats.

10 Q. Same information, just put in
11 different form?

12 A. That I used over the years.
13 Yeah, basically the same information. It
14 would be written in a different way.

15 Q. And I believe we were provided
16 with an updated copy of your CV; is that
17 correct?

18 MR. DAVISON: That's correct.

19 QUESTIONS BY MR. LOESER:

20 Q. Do you know what the difference
21 is between the version in your report and the
22 updated version?

23 A. Yes, it's publications.

24 Q. Okay. There's some additional
25 publications --

1 A. Yes, sir.

2 Q. -- on the updated version?

3 A. Yes.

4 Q. And were those publications
5 that you identified or counsel discovered and
6 added to your CV?

7 A. Some I identified and I think
8 you were provided a copy. Other, it was
9 counsel who found or located, because I don't
10 recall some of these.

11 Plus, we were in the middle of
12 a move. We just moved into a new house.
13 Everything's in boxes, which I have research,
14 so...

15 Q. Do you recall what publications
16 you discovered that were then added?

17 A. It was -- like I said, it was
18 the one you got today.

19 (Buzzeo Exhibit 5 marked for
20 identification.)

21 QUESTIONS BY MR. LOESER:

22 Q. We'll go ahead and mark that as
23 Exhibit 5.

24 Mr. Buzzeo, you're looking at
25 the updated copy of your CV that was provided

1 to us by counsel.

2 Can you turn to the
3 publications?

4 A. Yes.

5 Q. And, sir, can you identify for
6 us which additional publications you
7 discovered which were then added to this
8 list?

9 A. Number 1. I think that's the
10 one I found.

11 Q. And, sir, you've made sure that
12 this is a complete list of all publications
13 that you have authored?

14 MR. DAVISON: Objection.

15 THE WITNESS: This is not all
16 the publications I have authored over
17 the years, not at all.

18 QUESTIONS BY MR. LOESER:

19 Q. Do you have a list somewhere of
20 the publications that you've authored?

21 A. No.

22 Q. You haven't provided counsel
23 with a list of your publications?

24 A. No.

25 I don't recall most of them.

1 Q. Do you keep records of them?

2 A. No.

3 Especially after the move, I
4 have nothing except boxes. But I never kept
5 copies of anything.

6 Q. So this list of publications is
7 not actually complete?

8 A. It's not --

9 MR. DAVISON: Objection.

10 THE WITNESS: Oh, I'm sorry.

11 MR. DAVISON: Go ahead.

12 THE WITNESS: No, it's not.

13 As you can see, you got one
14 today that I just located.

15 QUESTIONS BY MR. LOESER:

16 Q. So your CV indicates for
17 education that you attended St. John's
18 University College of Pharmacy.

19 You received a BS in 1963; is
20 that correct?

21 A. Yes.

22 Q. And have you had any other
23 formal education since 1963?

24 A. Well, I was sent to University
25 of -- when I was with the Agency, University

1 of Rhode Island for a month on a
2 specialization course for manufacturing and
3 how to tablet manufactured product.

4 Q. I'm sorry, how to what?

5 A. How to manufacture products.

6 Q. Okay. And what products?

7 A. It was just general, when I was
8 with the Agency.

9 Q. How to manufacture controlled
10 substances?

11 A. A manufactured process given by
12 the University of Rhode Island.

13 Q. For drugs or for --

14 A. Oh, for drugs.

15 Q. -- chairs --

16 A. When I say "manufacturing," I
17 meant -- yes, to be clear, drugs.

18 Q. Okay. And did you receive a
19 certificate or anything for completing?

20 A. Oh, I probably received
21 something. I don't recall.

22 Q. And any other formal --

23 A. Oh, I'm sorry. Go ahead.

24 Q. Any other formal education
25 since then?

1 A. When we're talking formal, I
2 assume it's like something I just mentioned,
3 University of Rhode Island.

4 Q. Correct.

5 A. Yes.

6 No.

7 Q. In your areas of expertise in
8 your CV, the second to last bullet item is
9 opioid management guidance.

10 Do you see that on the first
11 page of your CV under areas of expertise?

12 A. Yes.

13 Q. Can you explain to me what
14 opioid management guidance is?

15 A. What I meant by any of these is
16 that from a regulatory perspective is, you
17 know, how do you look at your opioid
18 products, how do you manage it in an
19 operation, what kind of reporting do you do
20 with opioids, things like that.

21 Q. Who did you give opioid
22 management guidance to?

23 A. Our clients. We would talk to
24 them about it. Training sessions that we
25 would hold.

1 Q. So manufacturers, distributors,
2 chain pharmacies?

3 A. Chain pharmacies, physicians,
4 pharmacy groups.

5 Q. I want to try and quickly go
6 through your professional experience starting
7 with the first entry. Flip a couple of pages
8 into your CV.

9 It looks like you got your
10 start with the New York Department of Health
11 Bureau of Narcotics in 1966; is that correct?

12 A. Yes, 1966.

13 Q. And so from 1966 to '69, what
14 was your job?

15 A. I was an inspector for the
16 New York State Department of Health, Bureau
17 of Narcotics, Dangerous Drugs, or Bureau of
18 Narcotics. It was -- handled all controlled
19 substances.

20 I handled mainly Nassau -- I
21 think County of Nassau and Suffolk, if I
22 recall, and I was an investigator of, as I
23 say here, nursing homes, pharmacies,
24 hospitals. And then we did a lot of work
25 throughout the state on forged prescriptions

1 and even some undercover work.

2 Q. And was diversion part of what
3 you were looking for at that time?

4 A. That was it, it was drugs. And
5 the diversion part was the forged
6 prescriptions, which was a major problem at
7 that time when I was there in New York state.

8 Q. And then from 1969 through '72
9 you worked for the Bureau of Narcotics and
10 Dangerous Drugs, which then became the DEA;
11 is that correct?

12 A. Correct.

13 Q. And your CV says you were a
14 special agent?

15 A. I was special agent in
16 New York. I did a lot of undercover work,
17 worked a lot of clandestine labs. And then I
18 started getting new hires in their diversion
19 investigators, and so my group -- then I
20 became a group supervisor, so we handled both
21 illicit and licit.

22 Q. Okay. And what do you mean by
23 that?

24 A. I had agents that were handling
25 the illicit substances, heroin, cocaine,

1 marijuana, clandestine labs, and also -- and
2 the diversion investigators who were
3 regulating the pharmaceutical industry,
4 hospitals and pharmacies.

5 And then that was the time when
6 the implementing regulations came out, so we
7 did some -- right after that, we got involved
8 in that area.

9 Q. And so among the companies --
10 types of companies you were investigating,
11 you mentioned pharmacies.

12 Did you also investigate
13 manufacturers?

14 A. We would investigate the entire
15 distribution chain or -- and inspect -- in
16 those days it was doing a lot of inspections
17 because the new regulations were in place, so
18 we were doing a lot of inspections to ensure
19 that they understood what the regulatory
20 requirements were.

21 And we gave a lot of
22 presentations to the various registrant
23 groups.

24 Q. And what were the regulatory
25 requirements?

1 A. 13 -- the implementing
2 regulations for the Controlled Substances
3 Act.

4 Q. Can you elaborate on what those
5 regulations required?

6 MR. DAVISON: Objection.

7 THE WITNESS: We had
8 registration requirements, security
9 requirements, import/export
10 requirements, labeling, recordkeeping,
11 reporting requirements, inventory
12 requirements.

13 Those are some of the things
14 that we would sit down with, train,
15 offer assistance and also investigate.

16 QUESTIONS BY MR. LOESER:

17 Q. So moving down the timeline,
18 from '72 to '73 you were the group supervisor
19 at the DEA?

20 A. Correct.

21 Q. And you mentioned that -- how
22 would you -- your CV indicates that you
23 conducted criminal and regulatory
24 investigations of dosage, form and bulk
25 manufacturers, distributors and hospitals.

1 Is that accurate?

2 A. Yes.

3 Q. And how would you conduct your
4 investigations? What would you be looking
5 for?

6 MR. DAVISON: So I'm just going
7 to remind you not to get into the
8 actual confidential investigative
9 techniques of the DEA that you learned
10 during your time there because you
11 don't have Touhy authorization to
12 provide that information.

13 THE WITNESS: I'm going to
14 follow counsel's advice and not talk
15 about investigative techniques.

16 QUESTIONS BY MR. LOESER:

17 Q. So you were investigating for
18 diversion; is that correct?

19 A. As I had mentioned, I had -- I
20 had -- are we talking about headquarters or
21 the field now? In the head --

22 Q. Talking about the '72 to '73
23 when you were a group supervisor.

24 A. In the field.

25 So we had a mixed group, and

1 the agents were specializing in both domestic
2 and international cases associated with the
3 illicit substances.

4 The other group, the other half
5 I had, was diversion investigators who were
6 specializing in the regulated industry on
7 illicit substances.

8 If they ever had a case, the
9 diversion investigators, that seemed to be --
10 that was criminal in nature, some of the
11 agents -- I would assign some of the agents
12 to assist them.

13 Q. And in general terms, what kind
14 of diversion was occurring at that time?

15 A. Thefts, which included in
16 transit and sometimes employee thefts.
17 Maybe -- yeah, that was -- that was mainly
18 it, as I recall. I don't recall all the
19 types of investigations.

20 Q. Do you recall whether there was
21 diversion as a result of the failure of any
22 companies to have effective controls to
23 prevent diversion?

24 A. I'd like to talk to counsel
25 before I have some -- before I -- because of

1 the Touhy thing.

2 MR. DAVISON: Is it a Touhy
3 question?

4 THE WITNESS: Yeah.

5 MR. DAVISON: Let's go off the
6 record for a second.

7 MR. LOESER: Sure.

8 VIDEOGRAPHER: Off the record
9 at 10:13 a.m.

10 (Off the record at 10:13 a.m.)

11 VIDEOGRAPHER: We're back on
12 the record at 10:15 a.m.

13 QUESTIONS BY MR. LOESER:

14 Q. And, sir, do you have an answer
15 to the question I asked before?

16 A. Yes. It's -- just to clarify,
17 were there any manufacturers, or what was --
18 repeat your question.

19 Q. Sure. Why don't we...

20 Do you recall whether there was
21 diversion as a result of the failure of any
22 companies to have effective controls to
23 prevent diversion?

24 A. I'm going to give you a broad
25 response to that.

1 I recall -- I don't recall all
2 the details, but I recall we had one
3 situation where a company who's been -- was
4 put out of business as soon as we found out
5 about it, that was manufacturing during the
6 day. And at night they also manufactured,
7 and the stuff manufactured in the evening was
8 sent -- it was in the illicit market.

9 Now, this was a -- you know,
10 right when the regulations went into effect.
11 And, like I said, it's a criminal case made
12 against them.

13 And then there was another one
14 where -- yeah, there was another one where
15 the -- there was a company that was
16 supposedly exporting drugs, and they were
17 sent down to a location, I don't remember
18 where, someplace in the Southwest or
19 something, and it was never exported or
20 shipped to the licit market.

21 Those are two cases that I
22 remember.

23 Q. Okay.

24 A. And they were put out of
25 business very quickly, too.

1 Q. So moving to the next item on
2 your CV for professional experience, from
3 1973 to 1982 you were the head of
4 diversion -- head of the diversion prevention
5 program for the DEA?

6 A. Yes.

7 Q. Is that right?

8 A. Well, the -- yeah, the Office
9 of Diversion Control.

10 Q. And you note that this was a
11 new program, is that right, the diversion --

12 A. Yes.

13 Q. -- prevention program?

14 A. As I had mentioned earlier,
15 when I was in New York as a supervisor, I
16 started getting this newly trained workforce
17 of diversion investigators. And so then I
18 was asked if I would come down to Washington
19 and help develop this program, implement the
20 program, and I said, yes, I would.

21 And when I went to Washington,
22 I changed jobs series from special agent to
23 diversion investigator since I would now be
24 supervising a new program.

25 Q. And the description you have on

1 your CV says that you "implemented and
2 directed domestic and worldwide programs
3 associated with preventing the diversion of
4 legally produced controlled substances and
5 chemicals, formulating legislation and
6 regulations to curtail diversion and audit
7 and investigative procedures."

8 Did I read that correctly?

9 A. Yes.

10 Q. So, first of all, for purposes
11 of this job, how did you define diversion?

12 A. When drugs left the legitimate
13 distribution chain for illicit purposes, for
14 nonmedical use.

15 Q. Okay. And when you say
16 "drugs," you mean when controlled
17 substances --

18 A. Controlled substances, I'm
19 sorry.

20 Q. Yeah. And you mean when they
21 left control of the manufacturer or the
22 distributor, or who on the supply chain were
23 you investigating at that time?

24 A. It was -- a lot of the
25 diversion was at the practitioner level, by

1 physicians and pharmacy.

2 Q. Okay. And did you also
3 investigate diversion at the distributor and
4 manufacturer level?

5 A. There was a -- the field --
6 there was a routine program where they would
7 inspect the non-practitioner and also some
8 practitioner level to the new regulations.

9 And again, keep in mind, these
10 were in the new implementing regulations.
11 There was a learning curve. And so I was
12 working with the industry, the entire
13 distribution chain -- I should say, let's
14 make it easier, practitioner level and
15 non-practitioner level.

16 Q. And define what you mean by
17 that.

18 A. Non-practitioner level is
19 manufacturers and distributors, I think
20 researchers, too. And the practitioner level
21 would be your pharmacies, hospitals,
22 researchers, categories like that.

23 So there would be an inspection
24 program -- there'd be a training program,
25 training sessions, and also inspection

1 program working with the industry.

2 Q. And by "the industry," you mean
3 both the practitioners and the
4 non-practitioners?

5 A. Yes, sir.

6 Q. And so the training programs
7 applied to manufacturers and distributors and
8 to chain pharmacies as well?

9 A. Yes.

10 Q. And the training program would
11 train them on the principles of diversion?

12 A. The program was -- is we would
13 offer to an association or to individual
14 companies that we would come in and we would
15 work with them, or explain to them, what the
16 new regulatory requirements were, whether it
17 was security, whether it was on records,
18 whether it was on reporting. And also, you
19 know, would we accept what was currently in
20 place because of a -- previous regulations or
21 did they have to follow the new requirements
22 for security, let's say.

23 And it was working. It was
24 sort of -- I want to call it a compliance
25 program for the industry, for the

1 registrants, practitioners and
2 non-practitioners.

3 Q. And what were the requirements
4 that you explained to the manufacturers,
5 distributors and chain pharmacies with regard
6 to diversion?

7 A. The implementing regulations
8 that applied to that industry, just like we
9 would do for the non -- for the
10 practitioners --

11 Q. And do you recall any of the
12 specific requirements?

13 MR. DAVISON: Objection.

14 THE WITNESS: Security,
15 records, you know, registration
16 issues.

17 If it was a manufacturer, can I
18 distribute what I manufacture or would
19 I need a distributor registration, or
20 if I buy something and I distribute
21 that, do I need a -- can I do that
22 under coincident activity or
23 manufacturer -- it was issues such as
24 that we were involved in.
25

1 QUESTIONS BY MR. LOESER:

2 Q. And what about reporting
3 requirements?

4 A. Reporting requirements.

5 Q. What did you explain to
6 manufacturers, distributors and chain
7 pharmacies about reporting requirements?

8 A. I want to be careful I don't
9 get into the Touhy situations.

10 MR. DAVISON: Yeah, if it's
11 these general trainings, which it
12 seems you're talking about general,
13 it's fine to talk about the general
14 trainings, but not, you know, a
15 one-on-one investigation or anything
16 like that.

17 THE WITNESS: Yeah.

18 What we would talk about is,
19 let's say -- let's -- we'll talk about
20 security as a broad category.

21 Depending on the schedule, do I
22 need a vault, can I use an enclosure.
23 If I have an enclosure, like bulk
24 manufacturing, the whole building
25 would be considered controlled.

1 We'd get into maybe labeling
2 issues. We'd get into registration
3 requirements, you know, do you know
4 your customer's registered, things
5 like that. Loss in theft reporting,
6 suspicious order monitoring, whether
7 the regulation was 1301.74(b) about
8 reporting suspicious orders. You
9 know, just things like that.

10 QUESTIONS BY MR. LOESER:

11 Q. Elaborate on the last thing you
12 just said about reporting suspicious orders.

13 A. What the regulation was, you
14 know, manufacturer -- or registrants have a
15 requirement to report suspicious orders if
16 they meet certain -- such as, and it talked
17 about frequency, pattern, quantity.

18 Q. And you explained all of that
19 back in the '73 to 1982 time period?

20 MR. DAVISON: Objection.

21 THE WITNESS: '73 to '82, yes.

22 MR. DAVISON: And, Derek,
23 when -- sorry, I didn't mean to
24 interrupt. Whenever is a good time
25 for a break, we've been going a little

1 over an hour.

2 MR. LOESER: Okay. Go through
3 a few more things.

4 MR. DAVISON: That's fine.

5 QUESTIONS BY MR. LOESER:

6 Q. Your CV notes that you
7 implemented programs during this '73 to '82
8 time period.

9 What programs did you
10 implement?

11 MR. DAVISON: You can discuss
12 public programs that you have
13 implemented, but you can't discuss
14 nonpublic programs that you
15 implemented with the DEA.

16 THE WITNESS: We implemented
17 programs directed at the practitioner
18 level. That's a broad category.

19 QUESTIONS BY MR. LOESER:

20 Q. Okay. What about the
21 non-practitioner level?

22 A. The main part of our focus at
23 that time, the main part, was against the
24 practitioner level.

25 Q. Okay. And you mentioned that

1 you formulated legislation.

2 What legislation did you
3 formulate?

4 MR. DAVISON: And I'm just
5 going to, again, advise you if there's
6 any deliberative process that was done
7 regarding legislation or nonpublic
8 information, that's fine.

9 If it is legislation that is
10 public, you're fine to share that.

11 THE WITNESS: Yeah.

12 He was working -- one of them
13 that I recall had to do with the
14 Narcotic Addict Treatment Act and the
15 regulations associated with that. Had
16 to do with treatment programs.

17 NATA, National Association --
18 excuse me, addiction -- now you got me
19 confused. National -- NAT --
20 national -- I'm confused now. It's --
21 I'll have to -- I'll think about it.
22 I'll tell you later.

23 Narcotic Treatment Act. That's
24 it.

25

1 QUESTIONS BY MR. LOESER:

2 Q. And what about regulations?

3 You note that you formulated regulations.

4 A. Implementing regulations on the
5 NATA. And also, I was brought down to
6 Washington when I was still stationed in
7 New York to work on a committee that
8 implemented -- that was writing some of the
9 regulations, along with a team.

10 Q. Regulations for what?

11 A. Implementing -- for the CSA.

12 Q. For the Controlled Substances
13 Act?

14 A. Yes.

15 Q. And did you work on the
16 regulations pertaining to reporting?

17 A. The committee --

18 MR. DAVISON: Objection.

19 THE WITNESS: -- worked on most
20 of the regulations associated. The
21 committee was made up of legal, the
22 regulatory folks.

23 QUESTIONS BY MR. LOESER:

24 Q. And were you on the committee?

25 A. Yes.

1 Q. And do you recall what the
2 regulations required at that time with regard
3 to reporting?

4 A. Well, the regulations you see
5 is what we -- we wrote a lot of those.

6 Q. Okay. And did you advise
7 distributors and manufacturers and chain
8 pharmacies on the reporting requirements?

9 A. I don't recall whether -- what
10 was involved in it, but I know -- I recall
11 being on that committee to write those
12 regulations.

13 Q. And if you advised distributors
14 and manufacturers and chain pharmacies with
15 regard to the reporting regulations, would
16 you have done so accurately?

17 MR. DAVISON: Objection.

18 THE WITNESS: If we were
19 advising on regulations --

20 QUESTIONS BY MR. LOESER:

21 Q. Yeah. If you --

22 A. Now, if we --

23 Q. -- Mr. Buzzeo, advised
24 distributors and manufacturers and chain
25 pharmacies when you worked at the DEA with

1 regard to the reporting requirements, would
2 you have done so accurately?

3 MR. DAVISON: Objection.

4 THE WITNESS: The diversion
5 program, the Agency, if they're
6 advising the industry on the
7 regulations at that time, we would
8 advise them what the regulations said.

9 QUESTIONS BY MR. LOESER:

10 Q. So yes?

11 A. The answer is yes.

12 Q. Your résumé notes that you were
13 focused during this time period on curtailing
14 diversion.

15 What diversion were you focused
16 on curtailing?

17 A. As I recall -- could have been
18 others. As I mentioned, those other two
19 cases in New York, I was focusing on the
20 practitioner-level diversion.

21 Q. Your CV also notes for this
22 time period that you formulated audit and
23 investigative procedures.

24 Were those procedures for
25 investigating diversion?

1 A. The one I recall was for bulk
2 manufacturers, and I led a team of a chemist,
3 an accountant and myself, and we visited a
4 bulk manufacturer to develop the
5 accountability procedures for opium
6 processes.

7 MR. LOESER: We can take a
8 break.

9 MR. DAVISON: Take a break.

10 VIDEOGRAPHER: Off the record
11 at 10:28 a.m.

12 (Off the record at 10:28 a.m.)

13 VIDEOGRAPHER: We're back on
14 the record at 10:45 a.m.

15 QUESTIONS BY MR. LOESER:

16 Q. Mr. Buzzeo, looking more at
17 your CV, the entry for 1982 through 1990,
18 your position was deputy director for the
19 DEA; is that correct?

20 A. Yes.

21 Q. And what were your
22 responsibilities as deputy director?

23 A. Similar. Worldwide program,
24 registration, scheduling and quotas, ARCOS,
25 all of those requirements.

1 Q. And you mentioned ARCOS.

2 When did ARCOS come into being?

3 A. 19 -- well, it came into being
4 in the early '70s. When I got there in '73,
5 the program was being worked on, and that --
6 I was put in charge of that.

7 Q. And as deputy director, did you
8 oversee investigation of manufacturers?

9 A. We oversaw investigations
10 conducted by the field.

11 Again, let's go back to the
12 chain of command. The chain of command was
13 the program in the field reported to the
14 special agent in charge in each office. So
15 we provided from headquarters policy
16 guidance. That was mainly our function.

17 And also, if there was joint
18 investigations that covered many different
19 regions -- states, we would oversee that.

20 Q. And would you oversee
21 investigations?

22 MR. DAVISON: Objection.

23 THE WITNESS: Not in a manner
24 that we would be involved in the
25 investigation, but more in the policy

1 area or bringing together a number of
2 officers to work on similar type --
3 you know, cases, things like that.

4 QUESTIONS BY MR. LOESER:

5 Q. And so did you oversee policy
6 for the Controlled Substances Act as it
7 applied to manufacturers?

8 A. The entire distribution chain,
9 both non-practitioners and practitioners.

10 Q. So that would include
11 manufacturers?

12 A. That would include all the
13 registrants.

14 Q. And it would include
15 distributors?

16 A. Manufacturers, distributors,
17 chain pharmacies, independent pharmacies,
18 hospitals, physicians, stuff like that.

19 Q. And at that time did you help
20 set policy for the reporting requirements?

21 A. Yeah, I don't know if it was
22 policy, but direction to the field,
23 requirements to the field. But they had
24 their own structure also. Like I said, they
25 reported to a special agent in charge.

1 Q. And what were your directions
2 to the field in the 1982 to '90 time period
3 with regard to reporting requirements?

4 MR. DAVISON: And I'm going to
5 remind you of the Touhy obligations.
6 If there is public information that's
7 available, you can testify to that.
8 If it's nonpublic, the government has
9 not provided you Touhy authorization.

10 THE WITNESS: Any
11 requirement -- any requirements that
12 we involve -- that was involved with
13 the field that we were telling would
14 be confidential.

15 QUESTIONS BY MR. LOESER:

16 Q. Well, I'm asking you about your
17 guidance to the field, so that probably can't
18 be confidential, right?

19 A. We provided a lot of -- some
20 guidance to the field on the regulatory
21 requirements.

22 Q. Including the reporting
23 requirements?

24 A. Including all the requirements
25 of the CSA and implementing regulations.

1 From a regulatory perspective,
2 we had to have legal that would do any legal
3 issues that we would discuss jointly from a
4 legal perspective. We were providing
5 regulatory guidance, not legal.

6 Q. And were you careful to ensure
7 that the guidance you provided was accurate?

8 MR. DAVISON: Objection.

9 THE WITNESS: We were providing
10 regulatory guidance. We would have
11 discussions with legal, yes.

12 QUESTIONS BY MR. LOESER:

13 Q. So, yes, you were careful to
14 ensure the guidance you provided was
15 accurate?

16 A. Oh, yeah. Oh, yeah,
17 definitely.

18 And I should say this: If it
19 was policy, they'd be for the registrant.

20 Q. And what about suspicious order
21 monitoring programs, was that something for
22 which you provided policy guidance when you
23 were the deputy director of the DEA?

24 A. We would provide guidance on
25 all segments, and that's part of the

1 regulations.

2 Q. And do you recall what guidance
3 you provided to the field in the 1982 to '90
4 time period with the regard to the suspicious
5 order monitoring programs?

6 MR. DAVISON: And I'm also
7 going to remind you again of the Touhy
8 obligations. If it's public
9 information, you can provide it. If
10 it's nonpublic information or is
11 related to a nonpublic investigation,
12 you don't have Touhy authorization.

13 THE WITNESS: The way I'll
14 respond to that is that we provided
15 guidance, coordination, on all aspects
16 of the CSA in implementing regulations
17 from a regulatory perspective.

18 QUESTIONS BY MR. LOESER:

19 Q. And did you ensure that the
20 guidance that you provided with regard to
21 suspicious order monitoring programs was
22 accurate?

23 A. All the information that was
24 provided by headquarters was well-coordinated
25 and would be accurate.

1 Q. So, sir, you left the DEA in
2 1991; is that correct?

3 A. 1990.

4 Q. 1990.

5 And then did you -- it looks
6 like you started Buzzeo in 1991?

7 A. I believe it was '91.

8 Q. Okay. And why did you leave
9 the DEA?

10 A. I retired.

11 Q. I'm sorry?

12 A. Retired.

13 Q. Why did you retire?

14 A. I wanted to start my own
15 company.

16 Q. And why did you want to start
17 your own company?

18 A. Well, I saw a need. One is to
19 work with the industry in meeting the
20 regulatory requirements, and the second one
21 is, is that to ensure that there was
22 sufficient amount of controlled substance,
23 which -- in the practitioner. So there's
24 work with the industry and also the medical
25 need.

1 Q. And I'm sorry, sir, you said
2 you saw a need.

3 What was the need that you saw?

4 A. That -- you know, assisting the
5 industry in meeting the regulatory
6 requirements.

7 Q. And that need is different than
8 the need for the patients to obtain pain
9 medication?

10 A. It's -- it was also ensuring --
11 or working with the industry, also
12 assisted -- indirectly assist the patients in
13 meeting -- in obtaining -- you know, the
14 drugs were available to meet their medical
15 needs.

16 Q. And did you see those needs,
17 those two needs, as somewhat at odds?

18 A. At odds?

19 Q. Yeah, the guiding the industry
20 on compliance and ensuring access to opioids?

21 A. Not legitimate access, no.

22 Q. Okay. And so what you state in
23 your CV is that the purpose of Buzzeo was to
24 "provide guidance regarding implementing
25 regulations of the CSA," correct?

1 A. Correct.

2 Q. And what do you mean by that?

3 A. The implementing regulations of
4 the Controlled Substances Act and the impact
5 they had on the -- both practitioner level
6 and non-practitioner, the manufacturers, the
7 distributors, researchers, analytical labs,
8 hospitals, chain pharmacies, retail --
9 independent pharmacies, the whole
10 distribution chain, importers, exporters.

11 Q. And so you were providing
12 guidance to the entire distribution chain?

13 A. Not everyone. That would be a
14 couple million. But we had, you know, a nice
15 client base. I don't recall all of them.

16 Q. But in terms of the types of
17 registrants, you were providing guidance to
18 manufacturers, correct?

19 A. We probably touched everyone --
20 somebody from every part of that distribution
21 chain.

22 Q. So that would include
23 manufacturers?

24 A. Manufacturers, distributors.

25 Q. Pharmacies?

1 A. Practitioners, independent
2 pharmacies, chain pharmacies, researchers,
3 analytical labs, universities, states,
4 counties. Counties, yeah.

5 And some international issues,
6 import/export issues that impact the United
7 States or foreign countries.

8 Q. And when you say you provided
9 to states and counties --

10 A. It was counties, I should say.

11 Q. And what guidance did you
12 provide to counties?

13 A. We worked with one -- just
14 saying high level, one county, and I don't
15 recall, it was somewhere in the Southwest, I
16 think, where they brought us in to look at
17 how their county facilities were meeting the
18 regulatory requirements and handling
19 controlled substances.

20 And then we did some work
21 for -- where we inspected a number of jails
22 throughout the United States, how they
23 handled their controlled -- both as when they
24 brought somebody in that was going to be
25 imprisoned, put into prison, if they had any

1 drugs on them, how they handled that, and
2 also the health care they provided, how they
3 handled the controlled substances throughout
4 that process.

5 So those are -- those are --
6 even though the company -- a company hired us
7 who were supplying drugs to the jails, it's
8 still helping out -- they were county jails
9 and some state, and then the county that we
10 did out in the Southwest someplace.

11 Q. Okay. So the county you
12 referred to, you were actually hired by the
13 county?

14 A. We were hired by the county in
15 that situation.

16 Q. And the jail that you referred
17 to, you were not hired by the jail?

18 A. We were hired by a company that
19 supplied certain outsourced services to the
20 institutions.

21 Q. And what portion of your
22 consulting was for industry versus for public
23 entities?

24 A. Oh, probably a larger
25 percentage was in the -- the indus -- the

1 non -- between practitioners and
2 non-practitioners.

3 Q. And when you say the "larger
4 percentage," would you say over 90 percent?

5 A. I don't want to give you -- it
6 was a high percentage, but there may have
7 been some other non -- nonindustry people
8 that were involved, and I just don't recall.
9 But it was a high percentage.

10 Q. Okay. So you recall one
11 county?

12 A. One county.

13 Q. Do you recall any other?

14 A. I don't recall.

15 Q. Okay. And we're talking about
16 the time period 1991 through 2015.

17 So during that entire time
18 period you can recall one public entity for
19 which you provided consulting services?

20 MR. DAVISON: Objection.

21 THE WITNESS: That's all I can
22 recall.

23 QUESTIONS BY MR. LOESER:

24 Q. Okay. And so the rest of your
25 clients were from industry during that time

1 frame?

2 A. Except the jails. We did a lot
3 of due diligence work, but that would have
4 been with the industry.

5 Q. And the jail you mentioned was
6 also for the industry, right?

7 MR. DAVISON: Objection.

8 THE WITNESS: That was a
9 company that supplies services. Now,
10 did they supply anything else beside
11 the drugs, I don't recall.

12 QUESTIONS BY MR. LOESER:

13 Q. And, sir, without naming any
14 specific companies, during this time frame,
15 1991 to 2015, did you provide CSA guidance to
16 any companies that were investigated by the
17 DEA when you worked there?

18 MR. DAVISON: Objection.

19 THE WITNESS: I don't recall.

20 QUESTIONS BY MR. LOESER:

21 Q. So you may have --

22 A. But, again, keep in mind that
23 our function was to -- more proactive, was to
24 help companies meet the regulatory
25 requirements.

1 Q. So, sir, you don't recall
2 whether you did or did not provide guidance
3 with BuzzeoPDMA to any company that was
4 investigated by the DEA when you worked
5 there?

6 MR. DAVISON: Objection.

7 THE WITNESS: I don't recall.

8 QUESTIONS BY MR. LOESER:

9 Q. Now, your résumé indicates that
10 for BuzzeoPDMA you provided guidance.

11 Can you explain to me what you
12 mean by guidance?

13 A. There's the CSA, Controlled
14 Substances Act, and there's the implementing
15 regulations. So we would -- we would sit
16 down -- we would provide guidance on the
17 regulatory requirements and also industry
18 standards. And also any correspondence that
19 came out from DEA, we would discuss that with
20 them.

21 Now, we know the guidance on
22 SOM, suspicious order monitoring, has been
23 very -- there's been very little guidance on
24 that.

25 Q. And did you do anything else to

1 provide guidance to your clients when you
2 were with BuzzeoPDMA?

3 A. Oh, yeah. We did a lot of
4 outsource services.

5 Q. What does that mean?

6 A. Well, under the Prescription
7 Drug Marketing Act, there's a requirement
8 that inventories of sales reps be conducted,
9 so we would conduct the inventories of the
10 samples. We did reconciliation. They're
11 required to reconcile the samples on a
12 monthly basis, at least once a year.

13 We would provide those services
14 either on site or in our office, which some
15 of the companies in the controlled substances
16 area, if they had a need to, they would hire
17 somebody. Somebody left, we would provide
18 somebody that had certain expertise to handle
19 that program. Some of those assignments may
20 have lasted a week; some would last two
21 years.

22 So we did a lot of outsource
23 services as a company also, besides the
24 regulatory inspections that we did.

25 Q. Did you --

1 A. And -- excuse me. And also
2 registration. With some companies we
3 actually handled the state registration
4 requirements. Companies, in most states, are
5 required to get a license, out-of-state
6 license. Companies would outsource that
7 function to us.

8 Q. And did you operate the
9 suspicious order monitoring programs for any
10 companies?

11 MR. DAVISON: Objection.

12 THE WITNESS: No. Not that I
13 recall.

14 QUESTIONS BY MR. LOESER:

15 Q. So if you had operated any
16 suspicious order monitoring programs for
17 companies, would BuzzeoPDMA have some record
18 of that?

19 MR. DAVISON: Objection.

20 THE WITNESS: Yeah, but I don't
21 recall any that we did.

22 QUESTIONS BY MR. LOESER:

23 Q. Okay.

24 A. Again, I don't know if they --
25 but I don't recall in my time there any

1 programs in that area. Because that's
2 more of an, you know, immediate reporting
3 requirement if you -- once you determine it's
4 suspicious.

5 No, I don't think we ever did
6 that.

7 Q. And did you operate any
8 diversion control programs for any of your
9 clients?

10 A. We would inspect, but, no,
11 operation, no. No.

12 Q. Did you help your clients
13 respond to DEA investigations?

14 MR. DAVISON: Objection.

15 THE WITNESS: Respond, no, but
16 where we would be involved is if a
17 registrant had a regulatory issue and
18 we were retained, we would not contest
19 the findings, but we may look at it --
20 the future compliance where we would
21 do a report to say, this is what you
22 should be doing.

23 And some of those reports, I
24 understand, were shared with the
25 US Attorney or with state attorneys or

1 with DEA.

2 QUESTIONS BY MR. LOESER:

3 Q. And why would you not contest
4 the findings?

5 MR. DAVISON: Objection.

6 THE WITNESS: Because our
7 function was to look to the future and
8 make sure a company stays out of
9 problems, if they had a problem.

10 QUESTIONS BY MR. LOESER:

11 Q. Did anyone ever try to hire you
12 to contest the DEA's findings?

13 A. We would never do that.

14 Q. Why not? Why not?

15 A. We just wouldn't do it. We
16 decided that we weren't going to do that.

17 Our function was to either
18 ensure compliance or help them meet
19 compliance, or if they got in trouble, to put
20 together a regulatory program so they
21 wouldn't get in future trouble.

22 Now, we're talking about the
23 legitimate industry. If you were a diverter,
24 we wouldn't even touch you, even under those
25 circumstances.

1 Q. Did the DEA ever come to you to
2 ask you to help investigate compliance by a
3 DEA registrant?

4 A. No.

5 Q. In 2015, according to your CV,
6 your position with Buzzeo changed from chief
7 regulatory officer to senior consultant; is
8 that right?

9 A. It changed -- repeat your
10 question.

11 Q. Yeah.

12 If you look at the first page
13 of your CV --

14 A. Yes.

15 Q. -- in 2015 there's -- it
16 states, "2015 to August 2016, BuzzeoPDMA,
17 Inc., founder and senior consultant."

18 Do you see that?

19 A. What happened was, is when we
20 were acquired in 2005, I think it was, my
21 title changed, and I remained in that title.

22 So when I look at this, just to
23 be on the safe -- independent consultant now,
24 2015 to 2016, I was more or less the chief
25 compliance officer for the company. I

1 assumed the different positions from 2005 on.

2 Q. Okay. I want to make sure I
3 understand.

4 From '91 through 2015, you were
5 the chief regulatory officer, correct?

6 A. '91 to 2005, I was -- yeah,
7 chief regulatory officer. I founded the
8 company. I had -- I had a dual role because
9 once 2005 came together, then I switched
10 title. I wasn't the president of the company
11 any longer.

12 Q. Okay. So you were the
13 president up until 2005, but you were the
14 chief regulatory officer for the entire time
15 period '91 through 2015?

16 A. For that business unit, yes.

17 Q. Okay. And what was your job as
18 the chief regulatory officer?

19 A. Just to ensure that the
20 regulatory requirements that were discussed
21 by the company was accurate; to oversee some
22 of the reviews that were done, if they were
23 very detailed or -- you know, to do that.
24 From a business perspective, maybe sales
25 calls.

1 Or when I -- I don't mean sales
2 calls. From a business perspective, if the
3 company wanted to develop a new business
4 plan, they wanted to enter a certain market,
5 they wanted to ensure that they met the
6 regulatory requirements, I would sit down
7 with them. And from that perspective -- not
8 from a legal perspective, from a regulatory
9 perspective, these are the things they have
10 to do, meet with their attorneys, from the
11 business attorneys or the -- this regulatory
12 area. So from that perspective, that's what
13 I meant by that.

14 Q. So when you say "chief
15 regulatory officer," the regulatory you're
16 referring to is the Controlled Substances
17 Act?

18 A. And the PDMA.

19 Q. And the implementing
20 regulations for the Controlled Substances
21 Act?

22 A. And the Prescription Drug
23 Marketing, yes.

24 Q. And for BuzzeoPDMA, you were
25 the person in charge of making sure the

1 guidance provided to clients on the CSA and
2 its implementing regulations was accurate?

3 A. From -- for that period of
4 time, from when I sold the company in '05 to
5 I retired, I had a regulatory -- yes, a
6 regulatory function or an expertise function,
7 a training program function with the staff.

8 Q. Right.

9 So you would agree with me then
10 that during time period you were the person
11 in charge of making sure that the regulatory
12 guidance you gave to BuzzeoPDMA clients
13 regarding the CSA and its implementing
14 regulations was accurate?

15 MR. DAVISON: Objection.

16 THE WITNESS: Yeah, but keep in
17 mind it was a point in time that I
18 stopped going out in the field in some
19 situations, so I would provide -- make
20 sure the guidance being provided by
21 the staff was accurate, especially if
22 there was any written reports.

23 QUESTIONS BY MR. LOESER:

24 Q. Right.

25 You're saying that at one time

1 you provided the guidance, and you made sure
2 that was accurate, right?

3 A. Pending with state.

4 Q. Right?

5 And then later your staff
6 provided the guidance, but you made sure that
7 was accurate, right?

8 A. Correct.

9 Q. Okay. And currently -- sorry,
10 not currently.

11 In -- from 2015 through
12 August 2016, your position became senior
13 consultant, correct?

14 A. Yes.

15 Q. And how did your position
16 change between -- as senior consultant?

17 A. From -- August 2016, I retired.

18 Q. Right.

19 But from 2015 through
20 August 2016, you were the senior consultant,
21 right?

22 A. Oh, yes. Yes. Yes.

23 It was -- I went from -- then I
24 went -- from chief compliance officer I went
25 part-time, and I was just a senior

1 consultant. Again, the position really
2 didn't change, but since I went half-time, we
3 all felt that it would be better if I just
4 became a senior consultant.

5 Q. Okay. So your function was
6 basically the same; you were just doing it
7 less?

8 A. Somewhat, but only part-time.
9 I couldn't be involved in everything.

10 And they had -- there was
11 major -- like I said, more of in the business
12 area from -- if a company wanted to set up a
13 business plan or go in a different direction,
14 or acquisitions, things like that I was
15 mainly focused on.

16 Q. And just because you were part
17 time, you didn't stop caring if the guidance
18 that BuzzeoPDMA provided was accurate, did
19 you?

20 MR. DAVISON: Objection.

21 THE WITNESS: Well -- I'm
22 sorry.

23 MR. DAVISON: Go ahead.

24 THE WITNESS: It was different
25 because now I was more of a part-time

1 employee, so any guidance would be
2 provided by the company.

3 QUESTIONS BY MR. LOESER:

4 Q. Okay. And in terms of where
5 you were involved, you made sure the guidance
6 was accurate, right?

7 A. It was -- like I said, it was
8 from a business planning, acquisitions,
9 things like that.

10 Q. Fine.

11 But --

12 A. It was a little different.

13 Q. -- to the extent you were
14 involved, you made sure your guidance was
15 accurate, right?

16 MR. DAVISON: Objection.

17 THE WITNESS: Yes.

18 QUESTIONS BY MR. LOESER:

19 Q. And from August 2016 to the
20 present, you've been an independent
21 consultant?

22 A. Yes.

23 Q. And you left BuzzeoPDMA, Inc.,
24 why?

25 A. Well, I've been in this

1 business over 50 years. The wife and I
2 wanted to spend more time together and
3 travel. You reach a certain age, it's time
4 to fade off, ride off into the dust or the
5 evening.

6 And I didn't want to be full
7 time or part time. I wanted to have more
8 time to myself, but I wanted to keep my hand
9 in it. So there was a number of law firms I
10 consult with on regulatory requirements, not
11 legal requirements but regulatory
12 requirements. I don't even think I billed
13 for them.

14 Q. So basically what you're saying
15 is you retired from the company, but you
16 still do some consulting?

17 A. Yeah.

18 Q. And you mentioned law firms you
19 consult with.

20 What law firms do you consult
21 with?

22 MR. DAVISON: To the extent
23 it's privileged that you're working
24 on -- confidential that you're working
25 on specific things, I'll instruct you

1 not to answer.

2 THE WITNESS: Yeah, I think
3 I -- I'd like to say -- I'm going to
4 agree with my attorney. I'm not going
5 to mention it.

6 I wouldn't mention them unless
7 I got their approval, so I'm not going
8 to mention them.

9 QUESTIONS BY MR. LOESER:

10 Q. And the type of consulting you
11 do for law firms, is that with regard to the
12 regulatory requirements for DEA registrants?

13 A. Yes. Mainly in the
14 registration area.

15 Q. Okay. And tell me about the
16 consulting that you do now.

17 Who do you consult for now?

18 A. Some law firms.

19 Q. And any --

20 A. It's very casual.

21 Q. Any companies directly?

22 A. No.

23 Q. I want to make sure I
24 understand the corporate history of Buzzeo.

25 A. Okay.

1 Q. It started as Buzzeo

2 Associates; is that correct?

3 A. As I recall, Buzzeo Associates.

4 Q. And that was in 1991?

5 A. That would have been in --

6 yeah, '91.

7 Q. And then you started the

8 company called PDMA, Inc.?

9 A. Yes.

10 Q. And those companies merged in

11 the early '90s?

12 A. Yes, because we finally -- we

13 looked at it and said, well, gee, why would

14 we be two companies.

15 Hired a PR firm to come up with

16 a new name, and after spending a lot of

17 money, they came up with BuzzeoPDMA.

18 Q. And what did PDMA, Inc., do?

19 A. Excuse me?

20 Q. What did PDMA, Inc., do?

21 A. In to?

22 Q. What did it do?

23 A. Oh, Prescription Drug Marketing

24 Act of samples, physician samples. And we

25 worked with the companies that would sample

1 the products. And most of that was
2 noncontrolled substances.

3 Q. And did you evaluate companies'
4 samples for controlled substances?

5 A. Very few companies would sample
6 controlled substances.

7 Q. Why is that?

8 A. Because of the additional
9 regulatory requirements, the DEA
10 requirements. It was almost like you had to
11 maintain two recordkeeping systems.

12 No companies that I'm aware of
13 would sample a Schedule II because now not
14 only do they have the PDMA requirements for
15 records but you've got the 222 form. So
16 there was a hand -- I don't recall the
17 companies, maybe three or four companies,
18 that would sample even a Schedule III or IV
19 substance. Very few.

20 Q. And did you advise controlled
21 substances manufacturers that it was not a
22 good idea to provide free samples?

23 MR. DAVISON: Objection.

24 THE WITNESS: No, because

25 mainly -- no. If somebody -- like I

1 said, there were very few companies
2 that would even consider it. They
3 just didn't want to be -- it was the
4 recordkeeping system, which would have
5 been a double burden.

6 And a lot of the controlled
7 substances, as I recall, are generic.
8 And, you know, you get into a
9 pharmacy, you never know which
10 manufacturer you're getting if it's a
11 generic. And they can dispense any
12 generic product they want, that they
13 have in stock.

14 So companies really didn't
15 sample controlled substances.

16 QUESTIONS BY MR. LOESER:

17 Q. So BuzzeoPDMA was purchased by
18 Dendrite International, Inc., in 2005; is
19 that correct?

20 A. First acquisition was Dendrite,
21 which is a French -- no, Dendrite. Domestic
22 company.

23 Q. And do you recall what Dendrite
24 paid for BuzzeoPDMA?

25 A. Maybe roughly somewhere -- I'm

1 going to give you a range. About 12 to 15
2 million.

3 Q. And what portion of that was
4 paid to you directly?

5 A. Roughly maybe 6.

6 Q. 6 million?

7 And did you receive any other
8 compensation as a result of that sale from
9 Dendrite, any stock or anything like that?

10 A. No. No. We did give our three
11 managers a portion of that.

12 And I'll never forget the
13 president of the company said, "Ron, why are
14 you making such a low salary?"

15 And I said, "Well, we want to
16 pour money back into the company to build
17 it."

18 Q. What was your salary?

19 A. Back then?

20 Q. Yeah.

21 A. Hundred and something, maybe.

22 Q. And then in --

23 A. And when I finally retired,
24 before I went part time, it was maybe around
25 200. And when I went part time, it was

1 probably about 80.

2 Q. Okay.

3 A. When I had the company, we
4 wanted to do as much as we could for our
5 staff, so we gave them health insurance, we
6 gave them retirement plans. So that -- our
7 side story is I could have made a lot more
8 money when I sold the company if I didn't
9 consider my employees. And we didn't want to
10 do that. Either they take everybody or they
11 take nobody.

12 Q. How many employees were there
13 in 2005?

14 A. Rough guess, 80 to 90.

15 Q. And other than the other
16 managers that you mentioned, did any of the
17 sale proceeds go to those employees?

18 A. Excuse me?

19 Q. Other than the managers that
20 you mentioned, did any of the sale proceeds
21 go to those employees?

22 A. It went to my son.

23 Q. And what was your son's role?

24 A. He was the president, I think,
25 at the time. He was the president or senior

1 vice president.

2 Q. And so what amount was -- from
3 the sale proceeds was paid to your son?

4 A. He would have gotten the same I
5 received, give or take.

6 Q. Around 6 million?

7 A. Around 6 million. I could be
8 off.

9 Q. And how long did your son work
10 for the company?

11 A. Well, I have to tell people, I
12 built a business, he built a company. He was
13 very business-oriented.

14 God, I don't recall when he
15 came in. It was before we sold the company.
16 Probably -- I don't want to guess, but it was
17 before we sold the company. He was there --
18 he was there a period of time.

19 Q. He wasn't there at the
20 beginning?

21 A. No. God, no.

22 Q. And do you recall if he started
23 maybe after 2000?

24 A. Well, I started the company in
25 '90 -- 2000, I don't recall. It could have

1 been late '90s, early 2000.

2 Q. And did the work at BuzzeoPDMA
3 change at all as a result of the Dendrite
4 acquisition?

5 A. No, basically the business --
6 they maintained a separate business unit, and
7 it really didn't change.

8 Q. And did your responsibilities
9 change at all?

10 A. Well, yeah. My son became the
11 head of the company. They asked us who wants
12 to be president, and I said, "My son's got a
13 better business mind than I do." Let -- I'll
14 be chief regulatory officer for the -- for
15 that business unit, not for the whole
16 company.

17 Q. Right.

18 And then in 2007, Dendrite was
19 acquired by Cegedim; is that right?

20 A. Yes, a French company.

21 Q. Any idea how that sale came
22 about?

23 MR. DAVISON: Objection.

24 THE WITNESS: No. No. I
25 wouldn't be involved in that.

1 QUESTIONS BY MR. LOESER:

2 Q. And did you receive any
3 additional compensation as a result of that
4 sale?

5 A. No, I think the salary was
6 about the same.

7 Q. And did you receive any stock
8 or any other compensation?

9 A. No.

10 Q. And did the work that
11 BuzzeoPDMA performed change as a result of
12 the Cegedim acquisition?

13 A. We were doing international
14 work. Maybe we picked up additional
15 international because of its -- you know, the
16 holdings the company had.

17 Q. And then in 2015, Cegedim was
18 acquired by IMS Health; is that correct?

19 A. I think it was IMS, yeah, IMS
20 Health.

21 Q. And --

22 A. What year was that?

23 Q. 2015?

24 A. I don't recall the exact date,
25 but, yeah, IMS Health, I believe, was the

1 next acquisition.

2 Q. And do you have any idea how
3 that sale came about?

4 MR. DAVISON: Objection.

5 THE WITNESS: No.

6 QUESTIONS BY MR. LOESER:

7 Q. Were you familiar with IMS?

8 A. I know they were a data company
9 that provided prescription data, things like
10 that, but I think they provided a lot of
11 data.

12 Q. And did you utilize IMS data at
13 all in your work with BuzzeoPDMA?

14 A. I don't believe so.

15 Q. And did you receive any
16 compensation as a result of that sale to IMS
17 Health?

18 A. No.

19 Q. No stock or anything?

20 A. No.

21 Q. And the work of BuzzeoPDMA, did
22 it more or less stay the same following that
23 acquisition?

24 A. I don't recall.

25 Q. Can you estimate for me the

1 total amount you have earned as an industry
2 consultant for manufacturers, distributors
3 and chain pharmacies from 1991 to the
4 present?

5 MR. DAVISON: Objection.

6 THE WITNESS: It would be what
7 I sold the company for, plus the
8 little salary I was getting. No, I
9 couldn't estimate.

10 QUESTIONS BY MR. LOESER:

11 Q. Okay. Fair to say that the
12 total amount you earned is probably something
13 north of \$10 million?

14 MR. DAVISON: Objection.

15 THE WITNESS: I don't recall.
16 I mean, I'd have to add what I sold it
17 for and go back each year and add what
18 I made as salary.

19 QUESTIONS BY MR. LOESER:

20 Q. And the range of salary from
21 when you started until when you ended was
22 what?

23 A. Well, when I first started the
24 company, I was making nothing. I took all my
25 money out of retirement when I started,

1 worked at my dining room table, so I was
2 probably making hardly anything.

3 Q. That was year one?

4 A. Yeah, year one.

5 Q. Okay.

6 A. And then I took a large salary,
7 so maybe close to six figures, maybe, at the
8 beginning.

9 And like I said, the most I
10 probably ever made was maybe somewhere
11 between 150 to 200,000. Because when I
12 retired I -- give or take. I don't -- you
13 know, I'm just giving you estimates.
14 Probably 2,000 with bonus -- 200,000 with
15 bonuses just before I retired.

16 And then I went down to about
17 80,000 for a year or two and then...

18 Q. And what were your -- what were
19 you making the last year you worked for the
20 DEA?

21 A. Probably 80,000.

22 So it wasn't much more.

23 Q. On your CV under additional
24 relevant experience --

25 A. Yes.

1 Q. -- one of the items listed --
2 the third bullet point is "served as a member
3 of the National Advisory Committee to the
4 Robert Wood Johnson Foundation for Pain
5 Management and state regulatory policy"?

6 A. Yes.

7 Q. Do you know when you served in
8 that capacity?

9 A. No, I don't recall the dates.

10 Q. Do you recall what you did as a
11 member of that committee?

12 A. Yeah. Some recollection, but I
13 know it had to do with ensuring that the
14 regulatory requirements or policy didn't
15 impact with legitimate -- patient's
16 legitimate use, or legitimate use of opioids
17 and controlled substances for patient medical
18 needs.

19 And I, again, was put on that
20 committee, or asked to serve on that
21 committee, for the regulatory expertise that
22 I had.

23 Q. And do you recall if there were
24 members of industry that also participated on
25 that committee?

1 A. I don't recall who was on the
2 committee. I don't -- let's put it -- I
3 don't remember anybody, any industry people,
4 on the committee. But I don't recall. I
5 don't recall who was on the committee.

6 Q. Do you recall anything specific
7 about the work that you did on that
8 committee?

9 A. Making sure that the people
10 were getting sufficient controlled
11 substances, because there was a period of
12 time there where pain was undertreated.
13 Again, I'm not an expert in
14 that area. Just based upon what people have
15 said that were on this committee and other
16 presentations I've given that experts were
17 there. And, no. So they just -- it had to
18 do with -- my part was the regulatory
19 requirements, appropriate registrations,
20 physician training. Also, I think there was
21 some things there about the appropriate
22 prescribing, appropriate prescribing process.

23 Q. You mentioned a couple of times
24 that pain was undertreated.

25 What's the basis for your

1 statements that you thought pain was
2 undertreated?

3 A. Speakers that were on the
4 panels that I was on.

5 Q. Okay. And do you recall who
6 those speakers were?

7 A. Oh, God, there were some from
8 some of the cancer institution. No, I don't
9 recall.

10 Q. Do you recall if any of those
11 speakers were funded by the pharmaceutical
12 industry?

13 MR. DAVISON: Objection.

14 THE WITNESS: And to me, the
15 groups I was on was not funded by the
16 industry. Any money that was given, I
17 think -- I worked -- they worked it
18 out with the state. The state paid
19 everything. The state did everything.

20 QUESTIONS BY MR. LOESER:

21 Q. So is it your understanding
22 that the National Advisory Committee to the
23 Robert Wood Johnson Foundation for Pain
24 Management was not funded by industry?

25 A. I don't recall who funded that.

1 Q. Okay. Your CV also indicates
2 "extensive public speaking events for law
3 enforcement agencies, major pharmaceutical
4 companies, professional associations and
5 civics groups."

6 Can you tell me what major
7 pharmaceutical companies you spoke -- whose
8 events you spoke at?

9 A. I don't recall, but there was
10 law enforcement associations, there was
11 industry associations. Companies would hire
12 us to come in and give training programs to
13 their staff, the refresher presentations,
14 mainly the refresher, new hires on regulatory
15 requirements. Some of the sessions would
16 last an hour, some would last eight hours.
17 Associations, as I mentioned earlier, again,
18 the regulatory requirements, any changes in
19 policy that we were aware of, things like
20 that.

21 But I don't recall the
22 companies, and unless I had it in here, I
23 don't even recall the associations. But I'm
24 sure it was mostly health industry
25 associations.

1 Q. Okay. And so these major
2 pharmaceutical companies, would those have
3 been opioid manufacturers?

4 A. Controlled substance
5 manufacturers. I don't remember whether --
6 maybe it was just -- but it would be
7 controlled substance manufacturers. There
8 was -- it was some of those.

9 It was -- it touched -- what we
10 did touched the distributor chain. I
11 remember CE programs, pharmacy groups.

12 Q. Can you identify any specific
13 major pharmaceutical companies that put on
14 events where you spoke?

15 A. Like I said, I don't recall the
16 company. I know somebody -- it would have
17 been regulatory issues or PDMA issues. I
18 remember speaking to sales reps on the PDMA
19 issues.

20 So it's more the content
21 because I'm always involved in it, but not
22 really the company. I just don't recall.

23 Q. So you can't recall a single --

24 A. In 53 years there's a lot of
25 companies I was involved with, a lot of

1 registrants, both at the practitioner and
2 non-practitioner, chains, independents,
3 manufacturers, distributors, universities.
4 Did a lot of work with universities. I just
5 don't recall.

6 Q. So where your résumé notes
7 "major pharmaceutical companies," you can't
8 recall a single major pharmaceutical company
9 who put on an event at which you spoke?

10 MR. DAVISON: Objection.

11 THE WITNESS: I know there were
12 some, but I don't recall the names.

13 QUESTIONS BY MR. LOESER:

14 Q. Okay. Do you recall whether
15 you were paid to speak by any of these
16 pharmaceutical companies?

17 A. Some I would be paid; some I
18 would not be paid.

19 Q. And what would you be paid?

20 A. Some of the training we did as
21 a company, maybe 2,000, 3,000, plus expenses.
22 And not necessarily myself, a member --
23 you're talking about the company. It's other
24 members of the company.

25 Q. And so over these 50-plus

1 years, how many times were you paid 2 to
2 \$3,000 to speak on behalf of a pharmaceutical
3 company?

4 A. Most of my speaking was to
5 associations. Most of the speaking to
6 companies would have been handled by my
7 staff.

8 Q. Okay. And what associations
9 were you involved with?

10 A. NACDS, FMI, some of the
11 wholesalers -- it was in the wholesale
12 association that -- DWI or something, now
13 it's HDMA. That's mainly the American
14 Society of Consultant Pharmacists.

15 So mostly associations. So
16 safely I could give those names because it
17 was mostly associations.

18 Q. And so over your 50-plus years
19 in the industry, how much would you say you
20 were paid to speak at these events that you
21 mention your CV?

22 A. Well, my 50-years-plus included
23 three years as a pharmacist, three years with
24 the State of New York --

25 Q. Okay. Let's start with when

1 you were a consultant.

2 A. How much I was paid?

3 Q. Yeah.

4 A. Minimum. Not much. It was the
5 company pay. We didn't make much money on
6 training. It was a service.

7 Q. So 2 to \$3,000 per event.

8 And can you estimate the number
9 of events?

10 A. I can't.

11 Q. No idea at all?

12 A. I don't recall.

13 Q. Could have been a thousand?

14 A. Thousands?

15 MR. DAVISON: Objection.

16 QUESTIONS BY MR. LOESER:

17 Q. Yeah.

18 A. I don't recall. We made some
19 money on it, but it wasn't much at all. It
20 was more of a service program we gave.

21 When I became president of the
22 company, a lot of the decisions were -- I
23 wouldn't even get involved in.

24 Q. Your additional relevant
25 experience also notes that you "coauthored

1 the controlled substances regulatory guide
2 and compliance manual and CSA compliance and
3 counseling kit."

4 Do you see that?

5 A. Yes.

6 Q. When did you do that?

7 A. That would have been in the
8 early days, probably -- I don't recall the
9 exact date, but let's say probably in the
10 late -- maybe around 2000, that period of
11 time. I don't recall.

12 Q. And were you paid to do that?

13 A. No. But one was the CE
14 program, I believe. And so the CE program,
15 we did it through a university. I think for
16 that was -- they would get like \$25 and we'd
17 get a piece of that. So paid directly, it
18 was all through the university.

19 Q. What university?

20 A. Something -- someplace in
21 Georgia. I don't recall.

22 Q. Do you have any copies of
23 that --

24 A. I don't.

25 Q. Do you know where we could find

1 a copy?

2 A. Good luck, because I've been
3 looking through boxes that we had from
4 moving, and I can't find anything. No, I
5 don't have any copies.

6 And one of them was on a disk,
7 I do remember that. It was the size of a
8 business card.

9 And then one of the earlier
10 ones was a paper document.

11 Q. So with regard to the events
12 where you spoke, did you have any idea at the
13 time who was funding those events?

14 A. The association? They probably
15 got it from dues or something. I don't know.

16 Q. Or any of the events. For
17 example, where you spoke for major
18 pharmaceutical companies, were there
19 conferences that they put on?

20 A. Oh, we had conferences we put
21 on.

22 Q. And did industry put on
23 conferences as well?

24 A. The associations, some of the
25 ones I mentioned, yes.

1 In our conferences, we paid for
2 it.

3 Q. The last bullet on your
4 additional relevant experience states,
5 "Developed course entitled 'Preparing for the
6 DEA Pharmacy Audit for the Accreditation
7 Council for Pharmacy Education' in 2016."

8 Tell me about that.

9 A. We would -- one of the things
10 that we would train on was how to handle a
11 DEA audit, DEA pharmacy audit or a DEA --
12 anything in the distribution chain. You
13 know, it's like the DEA arrives, welcome
14 them, give them a pass if they need one, if
15 they need a pass, identify the person who has
16 been trained in that area of expertise to
17 handle that.

18 Same way when FDA goes in, the
19 staff that handles that. You know, how do
20 you handle DEA's questions. How do you -- if
21 they ask for certain records, make sure you
22 understand when they say "a distribution
23 record," what is a distribution record. If
24 they ask for a receiving record, what's a
25 receiving record.

1 After the review each night,
2 prepare a written memo report, things like
3 that.

4 And never lie.

5 Q. And are there written materials
6 for this 2016 course?

7 A. I wouldn't have anything. I
8 don't recall anything.

9 Q. You don't know --

10 A. You're talking about the last
11 bullet, right?

12 Q. Yeah.

13 A. Yeah.

14 Q. So for this 2016 course, you
15 don't recall if there are any written
16 materials?

17 A. I don't recall.

18 Q. And --

19 A. I don't have a copy.

20 Q. So the last thing on your CV is
21 a list of publications?

22 A. Yes.

23 Q. And we went through, you found
24 some more, they've been added, and that's in
25 your updated CV. We don't need to go over

1 that more.

2 All right. Let's look at
3 Exhibit B to your report.

4 And if you turn to the first
5 page after the slip sheet that says
6 Exhibit B, there's a document that starts --
7 that says, "Materials Considered."

8 Do you recognize this document?

9 A. Well, these are documents that
10 I've touched in some way.

11 Q. Okay. Can you page through the
12 whole materials considered list and just --
13 I'll ask you some specific questions, but
14 just flipping through the list, have you ever
15 seen this materials considered list before?

16 A. Oh, yeah.

17 Q. And did you create this list of
18 materials considered?

19 A. I gave the list to Ropes & Gray
20 to put into this format.

21 Q. Okay. So all of the items on
22 this list were things you told Ropes & Gray
23 to put on the list?

24 A. Yes.

25 Q. Okay. And what do you mean by

1 "considered"?

2 A. I reviewed it in detail or I
3 went through it and just picked out what I
4 thought was important or something. That's
5 what I mean by it, that I touched every one
6 of these.

7 And I don't mean physically,
8 physically touched, but reviewed it.

9 Q. And did you consider any
10 materials that are not listed in this
11 materials considered list for purposes of
12 preparing your report?

13 A. No.

14 Q. And you say you touched all the
15 items. You've read all of the items that
16 are on this list?

17 A. I've read -- I've read either
18 in detail or I read it and said, no, I really
19 don't need this particular document.

20 Q. And are there any items on this
21 list that you have not read at all?

22 A. No. And I utilized -- these
23 are the documents I utilized in preparing my
24 report.

25 Q. So Mallinckrodt has produced I

1 think over 9 million pages of documents in
2 this case.

3 How did you select these
4 particular documents that have this
5 Mallinckrodt Bates stamp from those 9 million
6 pages?

7 A. Good question.

8 There was things that I would
9 ask for. Once I found out what the purpose
10 of me being retained was, to look at their
11 compliance program associated with suspicious
12 order monitoring, there are certain documents
13 that I requested. And the other documents is
14 what counsel provided me for my project.

15 Q. So looking at this list of
16 Mallinckrodt Bates numbers, which are the
17 ones you requested?

18 Going back to the very first
19 page of your materials considered.

20 A. Yeah.

21 Q. I'll ask you about the other
22 sections, but if you go back to the first
23 page --

24 A. Well, on those -- those -- the
25 first page, those were provided by counsel,

1 that they felt that I needed these in order
2 to complete the assignment that I had.

3 Q. Okay. So all of the documents
4 that bear a Bates stamp MNK-T1 and then a
5 number, those are items that counsel provided
6 to you?

7 A. Yeah. But it's also probably
8 based upon -- you know, you've asked me to
9 look at Mallinckrodt's SOM program. I want
10 to see everything associated with that so I
11 can make an independent decision on that
12 program. And these are some -- these would
13 be the documents that they would provide me.

14 Q. Okay. So you asked for
15 everything --

16 A. That was a very broad question
17 of things I wanted to see that applied to the
18 program.

19 Q. Okay. So you asked for
20 everything related to Mallinckrodt's program,
21 and what you got were the documents listed in
22 your materials considered with the
23 Mallinckrodt Bates number?

24 A. Correct.

25 Q. Did you get all of these all at

1 once, or were these things that were given to
2 you over time?

3 A. No, they kept coming to the
4 house over time. One day I'd get two boxes,
5 next day maybe three boxes.

6 Q. Okay.

7 A. Maybe another box.

8 Q. And you didn't make any effort
9 to review Mallinckrodt's production generally
10 to find other materials than the ones that
11 Mallinckrodt identified for you?

12 A. I asked for documents that I --
13 based upon my 50-plus years of experience
14 that I would need in order to review their
15 program and render a decision.

16 Q. And did you have any concern
17 that Mallinckrodt was cherry-picking
18 particular documents for you and not showing
19 you documents that would have been damaging
20 to Mallinckrodt?

21 A. I have no reason to expect
22 that -- to suspect that.

23 Q. Okay. You didn't have any
24 concern about that?

25 A. None whatsoever.

1 Q. And you didn't ask whether that
2 occurred?

3 A. Oh, I did ask, "Am I being
4 shown everything that I need in order to
5 review this and render an opinion" based
6 upon, as I mentioned earlier in my expert
7 opinion, they meet the requirements.

8 Q. Okay. And you made that
9 decision based upon this list of Mallinckrodt
10 documents in your materials considered list?

11 A. Based upon my review of these
12 documents, I made that decision.

13 Q. And did you make sure that all
14 of these documents that are listed here, and
15 again, the Bates-stamped documents, were
16 complete, that you hadn't been given some
17 part of a document but not the whole thing?

18 A. I have no reason to suspect
19 that. Plus, when I read some of the
20 depositions from some of the plaintiffs'
21 experts, there was documents that were
22 utilized in there, and I asked for copies of
23 those and made sure I got those. So I have
24 no reason to suspect that any of these
25 documents are tampered with, I would say.

1 Q. And as you've said, you've
2 looked at every single one of these
3 documents?

4 A. I've looked at them.

5 Q. And none of them are
6 incomplete?

7 A. Not to my knowledge.

8 Q. Okay. And every one is a
9 document that pertains to Mallinckrodt's
10 suspicious order monitoring program?

11 A. Yes.

12 Q. And if you had received one of
13 these files and you saw that it was
14 incomplete or did not contain anything, you
15 would have asked for the document that was
16 identified?

17 A. If I received something that
18 didn't apply, you know, after I've requested
19 certain documents, I would say to them, "Hey,
20 this is not what I asked for. I asked for
21 something that touched the SOM program for a
22 period of time." And so -- but that never
23 happened.

24 Q. And these were hard copy
25 documents that were sent to you?

1 A. Yes.

2 Q. Okay. And did you put these
3 documents in a binder or try to organize them
4 in some way?

5 A. I didn't put them in a binder.
6 I received them in a binder.

7 Q. Okay. And did you take any
8 notes on the documents?

9 A. Like I said earlier, when I
10 prepare my reports, I like to take -- like to
11 take notes. So depending on what I was
12 reading, I may only put a sticky in so I knew
13 that I read that page.

14 In some cases if I thought,
15 "Gee, this would be helpful in my report, my
16 evaluation in my report," I would make a note
17 on the sticky or actually write out a
18 paragraph or something so that I could
19 consider it for my future report.

20 Q. So in just flipping through
21 this list of Bates stamps, the very first one
22 says ABDC MDL.

23 Do you know what that document
24 is?

25 A. Oh, I don't recall.

1 Q. In judging from the Bates
2 number, it was not produced by Mallinckrodt.

3 So can you tell me, did you
4 review -- other than what's on this list, did
5 you review any documents that were produced
6 by any other defendant in this case?

7 A. No. No. Everything I've done
8 has just been for the Mallinckrodt, who
9 retained -- for Ropes & Gray, who retained
10 me.

11 Q. Now, the next item in the
12 materials considered list is portions of
13 deposition transcripts and certain exhibits.

14 Do you see that?

15 A. Yes.

16 Q. And I've counted, and it looks
17 like there's 19 deposition transcripts that
18 are indicated here?

19 A. Yep. Yes.

20 Q. And this notes that you
21 reviewed portions of these transcripts; is
22 that accurate?

23 A. Some of the transcripts, as I
24 started reading, I said this is -- this is
25 what I need in detail, and I read it in

1 detail.

2 Q. So how did you choose these
3 deponents?

4 How did you choose these
5 transcripts to review?

6 A. When I asked -- I said, look,
7 you retained me to look at Mallinckrodt's SOM
8 program. I need to have at my disposal
9 everything that's going to help me render a
10 decision, whether it's good or whether it's
11 bad. And these are the documents that they
12 applied.

13 The other thing I asked them
14 was, "Look, you tell me that there's
15 plaintiff depositions that could impact
16 Mallinckrodt. I asked -- I want to see
17 copies of that. And anything that DEA
18 provided in the way of depositions or
19 information, I want to see those."

20 That's how this came about.

21 Q. Okay. And so you --

22 A. And I said, "Assure me -- or
23 make sure that I get every document that I
24 need in order to render a decision."

25 Q. Okay. So you relied on

1 Mallinckrodt to provide you with, as you say,
2 every document that would help you with your
3 decision?

4 A. Not Mallinckrodt. Ropes &
5 Gray. All my discussions have been with
6 Ropes & Gray.

7 Q. Okay. So you relied on
8 Mallinckrodt's lawyers to provide you with
9 every document that you need to make your
10 decision?

11 MR. DAVISON: Objection.

12 THE WITNESS: I relied on
13 Ropes & Gray to provide me with
14 documents, yes.

15 QUESTIONS BY MR. LOESER:

16 Q. Okay. And as I asked before,
17 you read portions of these deposition
18 transcripts; is that right?

19 A. Some of them I read --

20 MR. DAVISON: Objection.

21 THE WITNESS: -- in detail.
22 Some I read in -- portions of it.

23 QUESTIONS BY MR. LOESER:

24 Q. Okay. Which ones did you --
25 did you read all of any of them?

1 A. Some of them I read in detail.

2 Yes, I've read all of them, but some in
3 detail; some not.

4 Q. So you've read every page of
5 all of these depositions?

6 A. I didn't say that. I said some
7 of them I've read in detail, others I just
8 read portions of, depending on what I felt I
9 needed in evaluating Mallinckrodt's program.

10 Q. Have you read every page of any
11 deposition on this list?

12 A. Yes.

13 Q. Which ones?

14 A. McCann, Whitelaw, Rafalski and
15 Kelly {sic}, I think it was.

16 Q. Okay.

17 A. And just -- some of the things
18 that Joe Rannazzisi said I read in detail.

19 Rafalski, I think I said that.

20 So there's some other I just
21 don't recall.

22 Q. So of the 29 depositions on
23 this list --

24 A. Oh, pre -- I can never
25 pronounce his name, Prevoznik or whatever the

1 heck it is, p-r-e-v-o-z-n-i-k.

2 Stewart, I read a number of
3 sections of that one. Yeah.

4 Q. Okay. So you mentioned -- I
5 lost count, but was it five that you read in
6 full?

7 MR. DAVISON: Objection.

8 THE WITNESS: Yeah. Give or
9 take, yeah. I'd say that.

10 QUESTIONS BY MR. LOESER:

11 Q. Okay. And the rest you read
12 parts?

13 A. Parts that I thought was
14 appropriate for what I was assigned.

15 Q. Are there any that you didn't
16 read at all?

17 A. No, I think I touched every one
18 of these.

19 Q. Okay. Which are the ones that
20 you just skimmed a little bit?

21 A. Oh, God. Harper was another
22 one I read in full detail. Karen Harper.

23 Q. And when you say "full detail"
24 you mean --

25 A. I read the whole report.

1 Q. Okay.

2 A. Stacy Harper from DEA, I only
3 read partial, partial sections of it.

4 Q. Well, let me make this easier
5 for you.

6 Are there any on here that you
7 just barely skimmed?

8 A. No, there was -- I think every
9 one of them I read portions of it. I
10 wouldn't say barely skimmed. You know, I
11 read maybe 10 percent, maybe 20 percent of
12 it. I'd skim through and say, "Wait, this is
13 a section that I want to really read in
14 detail."

15 Q. And how did you choose which
16 portion to read?

17 A. Again, looking -- recalling
18 what I was assigned to do, based upon that,
19 that's how I would determine what I'm reading
20 in detail and what I'm not.

21 Q. Did you ask Mallinckrodt's
22 lawyers to identify the portions that you
23 should read?

24 A. No, not at all.

25 Q. So all of the portions you read

1 were as a result of your skimming these
2 depositions and focusing on certain sections?

3 A. Yes, it's what I determined I
4 thought was appropriate for me to review so I
5 could render a decision on Mallinckrodt's
6 program.

7 Q. And no one told you to review
8 one portion or another?

9 A. No.

10 MR. DAVISON: Objection.

11 THE WITNESS: I wouldn't -- I
12 wouldn't have accepted that.

13 QUESTIONS BY MR. LOESER:

14 Q. And in your report when you
15 refer to the depositions and you quote them,
16 were those quotations things that you found
17 on your review?

18 A. Yes.

19 Q. All of them?

20 A. Yes.

21 And then they would put the
22 number in and the number down. So, yeah, I
23 gave them, said, "This is the footnote I want
24 in this report. This is what I -- or this is
25 what I reviewed," and then they would put it

1 in the report for me.

2 Q. What does that mean?

3 A. What that means is --

4 MR. DAVISON: Objection.

5 THE WITNESS: -- when you read
6 the report, it refers to a number, 136
7 or something.

8 QUESTIONS BY MR. LOESER:

9 Q. Right.

10 A. That was part of the -- that
11 was something I reviewed for my report.

12 And as I said earlier, we
13 discussed this earlier this morning,
14 that's mentioned in the footnote and
15 mentioned in the report.

16 Q. So you would say -- you would
17 provide some testimony that you wanted
18 included, and then they would find where that
19 testimony was?

20 A. No, I found it --

21 MR. DAVISON: Objection.

22 THE WITNESS: -- and told them,
23 "This is what I reviewed for my
24 report."
25

1 QUESTIONS BY MR. LOESER:

2 Q. Okay. And they would provide
3 the citation in the report?

4 A. They would put the footnote in.

5 Q. Okay. Your materials
6 considered has a list of expert reports under
7 the expert materials?

8 A. Yes.

9 Q. And did you choose -- how did
10 you choose those particular experts?

11 A. Well, it's -- I wanted
12 testimony from the plaintiff side that
13 referred to Mallinckrodt, so these are some
14 of the depositions -- these are the
15 depositions that I received in that case.

16 And then I said to them, I want
17 to see all the attachments that are in those
18 depositions and other documents that you may
19 have that will allow me to render a decision
20 on Mallinckrodt's program.

21 Q. So you told Mallinckrodt's
22 counsel generally what you were looking for,
23 and they identified these specific experts
24 and gave you those reports?

25 A. Yes.

1 Q. And did you read every page of
2 each of these reports?

3 A. This list, yes.

4 Q. And you read all the materials
5 as well?

6 A. Yes.

7 Q. Attached materials?

8 A. Yes.

9 The one I didn't was the last
10 one here, expert report of Edward -- I only
11 skimmed that.

12 Q. How long did you say you took
13 to skim that report?

14 A. Oh, I don't know. I think the
15 total hours I put on my expense account I
16 think is what, 172 hours. That's all it
17 took.

18 Q. But you don't recall the amount
19 of time you spent --

20 A. No.

21 Q. -- skimming --

22 A. No.

23 Q. -- the Buthusiem report?

24 A. No.

25 Q. And so these reports listed

1 here, these are the ones that you address in
2 your report; is that right?

3 A. This -- a lot of these
4 materials are addressed in the report.

5 Q. But these expert reports are
6 the ones that your report responds to?

7 A. Well, no, I also -- some of the
8 others, Joseph Rannazzisi --

9 Q. No, I'm asking you specifically
10 about the expert materials, and there's a
11 list of seven.

12 A. Oh, yeah, but there's others
13 that I've read in detail.

14 Q. You read other expert reports?

15 A. These, what's in here.

16 Q. Those are depositions.

17 A. I know that.

18 Q. Okay.

19 A. Okay. You just asking about
20 the expert -- this material, yeah.

21 Q. Those are the expert reports
22 that you reviewed?

23 A. Yes.

24 Q. And you didn't review any other
25 ones?

1 A. No.

2 Q. Do you know how many others
3 there are in this case?

4 A. No.

5 Q. Did you ever ask to see any
6 expert reports other than these ones on this
7 list?

8 A. Like I said, my general
9 question was -- to them was, "Provide me with
10 all documents that I need in order to render
11 a decision on Mallinckrodt's program."

12 Q. And in response to that
13 question, among other things, Mallinckrodt
14 provided you -- or their counsel -- with this
15 list of expert reports?

16 A. They provided me with this
17 material, yes.

18 Q. And so are there any other
19 expert reports that your report responds to?

20 A. No.

21 MR. DAVISON: And, Derek, we've
22 been going another hour, so whenever
23 is a good time, just --

24 MR. LOESER: Okay. We'll just
25 finish this.

1 MR. DAVISON: That's fair.

2 QUESTIONS BY MR. LOESER:

3 Q. The next thing in your
4 materials considered are case documents?

5 A. Yes.

6 Q. And there's a list of
7 pleadings.

8 Did you select this list?

9 A. Again, it was based upon my
10 general question of what I needed, and these
11 are the documents that I was provided.

12 Q. Okay. So this is another
13 category of information that you relied on
14 Mallinckrodt's counsel to provide to you so
15 that you could prepare your report?

16 A. Yes, sir.

17 Q. And did you read all of these
18 documents?

19 A. Again, I read a lot of the
20 detail. Others I may have just read portions
21 of it.

22 Q. Are there any that you didn't
23 read at all?

24 A. No, I touched every one of
25 them.

1 Q. And how did you choose which
2 portions to read?

3 A. When I started the report, I
4 skimmed and said, "Yeah, I think I better
5 read this in detail."

6 Some were...

7 Q. A couple of these items just
8 list specific interrogatory numbers.

9 Do you see that?

10 A. Yes.

11 Q. How did you choose those
12 interrogatories?

13 A. Again, based upon what I was
14 assigned to do or asked to do, requested to
15 do. In reading it, those are the ones I felt
16 was appropriate.

17 Q. So did Mallinckrodt's counsel
18 identify these particular responses?

19 A. No.

20 Q. So you --

21 A. They provided the documents
22 based upon my general question, and then I
23 looked at -- when I would look at it, I'd
24 say, "Yeah, this is something I want to maybe
25 touch on my report."

1 Q. Now, all of these case
2 documents that are listed are discovery
3 responses by Mallinckrodt; is that right?

4 A. Uh-huh.

5 Q. And are you aware that other
6 parties also responded to discovery in this
7 case?

8 A. No.

9 Q. So you didn't read any
10 discovery responses by any other defendant?

11 A. No. Like I said, everything
12 is here.

13 Q. Okay. So you didn't read any
14 discovery responses by the plaintiffs in this
15 case?

16 A. No.

17 Q. You didn't think that was
18 something that would be worth taking into
19 account when --

20 A. No.

21 Q. -- reaching your decision?

22 MR. DAVISON: Objection.

23 THE WITNESS: No. Like I said,
24 what I was asked to do or requested to
25 do, I felt that I had the material

1 here to render a regulatory opinion
2 based upon my expertise.

3 QUESTIONS BY MR. LOESER:

4 Q. Okay. Moving on to cases and
5 statutes, the last page of your materials
6 considered.

7 A. Yes.

8 MR. LOESER: And then, Counsel,
9 we'll take a break right after we're
10 through this.

11 QUESTIONS BY MR. LOESER:

12 Q. This lists -- cases and
13 statutes lists 18 items. And how did you
14 come up with this list?

15 A. Again, it comes back to what I
16 was asked to do and how I put the question to
17 them. These are some of the things I wanted
18 to see, especially -- and I did ask them
19 specifically, if there's anything that DEA
20 provided in the way of testimony or reports
21 or something, I want to see those documents.

22 Q. Okay. So this is another list
23 that was -- these items were selected by
24 Mallinckrodt's counsel in response to your
25 question for all information that you needed

1 to form your opinion?

2 A. Yes.

3 MR. DAVISON: Objection.

4 QUESTIONS BY MR. LOESER:

5 Q. And so it was not you that
6 identified the bench trial transcript, United
7 States v. Four Hundred Sixty Three Thousand
8 Four Hundred Ninety Seven Dollars and Seventh
9 Two Cents; it was Mallinckrodt's counsel?

10 A. Based upon the general question
11 that I asked them, yes.

12 Q. And would the answer to that
13 question be the same for each of the items on
14 this list?

15 A. Yes.

16 Q. And prior to this case, did you
17 have any familiarity with United States v.
18 Four Hundred Sixty Three Thousand, that
19 matter?

20 A. Which one now?

21 Q. The first item on that list,
22 bench trial transcript.

23 Do you see that?

24 A. This was -- no. This was based
25 upon my general question. This is one of the

1 documents that was provided. I don't recall
2 I had any prior knowledge.

3 Q. Okay. And you'll see that
4 there's a couple entries there for the
5 Masters Pharmacy, Inc. v. Drug Enforcement
6 Administration?

7 A. Uh-huh.

8 Q. Did you have prior knowledge of
9 that case?

10 A. I was aware of the Masters
11 case.

12 Q. And how were you aware of it?

13 A. It was in the Federal Register,
14 and I just -- how I came about it was like
15 the Southwood one also. It's just -- it was
16 a well-known -- those are well-known cases.

17 Q. And did you consider the
18 Masters case an important case in the area of
19 Controlled Substances Act compliance?

20 MR. DAVISON: Objection.

21 THE WITNESS: I looked at it
22 and considered it, as I did Southwood,
23 as I did the regulations.

24 QUESTIONS BY MR. LOESER:

25 Q. So for those two cases, Masters

1 and Southwood, would you agree that those are
2 important cases in the area of Controlled
3 Substances Act compliance?

4 MR. DAVISON: Objection.

5 THE WITNESS: They're cases
6 that should be read, and there's some
7 importance to it. I don't want to --
8 I don't want to downplay it, but it
9 has a role.

10 QUESTIONS BY MR. LOESER:

11 Q. And what's that role?

12 A. Role is when you're dealing
13 with the regulations and the industry and the
14 Agency, you want to know as much as you can
15 and what the consideration is, especially in
16 this case, like Masters or Southwood, what
17 was the -- what was the comments and
18 testimony, what was the considerations. You
19 want to look at it from that perspective.

20 Does it change any
21 recommendations you want to make, general
22 recommendations, to companies, to the
23 industry, to practitioners,
24 non-practitioners, things like that.

25 Q. And did those cases change

1 recommendations that you made?

2 MR. DAVISON: Objection.

3 THE WITNESS: I don't recall,
4 but if I felt -- we felt it was
5 important, we would have made maybe
6 some recommendations.

7 QUESTIONS BY MR. LOESER:

8 Q. But you don't recall whether
9 you did that or not?

10 A. I don't recall.

11 Q. Do you agree that these
12 decisions provide important guidance on how
13 to identify orders that are unusual or not
14 normal?

15 MR. DAVISON: Objection.

16 THE WITNESS: Well, the
17 important guidance is what the
18 regulation says and the letters that
19 DEA came out.

20 Now, in the guidance of letters
21 is, you know, it's not policy, it's
22 just a guidance document. But those
23 are -- those are important, because
24 that gives you the -- how the --
25 possibly how the Agency is thinking.

1 QUESTIONS BY MR. LOESER:

2 Q. And, sir, do you believe that
3 the Masters case and the Southwood case
4 provide important guidelines on how to
5 specifically identify orders that are unusual
6 or not normal?

7 A. Well, they provide important --

8 MR. DAVISON: Objection.

9 Wait until he finishes.

10 THE WITNESS: Could you repeat
11 your question?

12 MR. LOESER: Can you read the
13 question back, please?

14 (Court Reporter read back
15 question.)

16 QUESTIONS BY MR. LOESER:

17 Q. And let me modify the question
18 slightly.

19 Instead of guidelines,
20 guidance. Important guidance.

21 A. Important guidance?

22 Q. I'm sorry, I'm speaking.

23 A. Like one of the things that
24 sticks out in my mind is the quantities that
25 were being sold. So from a perspective when

1 you look at that, that could be one thing you
2 should consider.

3 So from that perspective, yeah,
4 it did provide insight into the whole issue
5 of suspicious order monitoring.

6 Q. And so you'd agree that it
7 provides -- the decisions provide important
8 guidance?

9 MR. DAVISON: Objection. Asked
10 and answered.

11 THE WITNESS: The what?

12 QUESTIONS BY MR. LOESER:

13 Q. Important guidance?

14 MR. DAVISON: Objection. Asked
15 and answered.

16 THE WITNESS: I didn't hear
17 what you said.

18 MR. DAVISON: I just said
19 "objection."

20 You can answer.

21 THE WITNESS: Oh. It
22 provides -- it provides some guidance,
23 especially when you start looking at
24 the quantities involved. Yeah.

25

1 QUESTIONS BY MR. LOESER:

2 Q. And did you provide guidance to
3 your DEA registrant clients regarding the
4 Masters case?

5 A. What we provide is the
6 regulatory requirements, industry standards.
7 And when we receive -- like we reviewed one
8 of these reports, and I don't recall the
9 whole detail of either the Masters or
10 Southwood except what sticks out in my mind
11 about the quantities. We would talk about it
12 with our clients.

13 And we may say, "Gee, based
14 upon our understanding, in order -- you may
15 want to consider, you know, doing something
16 else with your program."

17 But, yeah, so I would say yes.
18 You know, knowledge is important, especially
19 when you're dealing in a regulated industry
20 with both practitioners and
21 non-practitioners.

22 Q. And do you recall if the
23 Masters decision evaluated whether
24 prescriptions were legitimate as opposed to
25 just the quantity of the orders?

1 A. I don't recall all the details
2 of it. It was a while ago since I looked at
3 it.

4 Q. When's the last time you read
5 the Masters decision?

6 A. Excuse me?

7 Q. When was the last time you read
8 the Masters decision?

9 A. About a month ago, month and a
10 half ago.

11 Q. Very last thing on your
12 materials considered list are reports, public
13 documents and studies.

14 Same question on this: Is this
15 a list of items that was created by
16 Mallinckrodt's counsel, or is this a list
17 that you came up with?

18 MR. DAVISON: Objection.

19 THE WITNESS: Some of these are
20 what I requested, and some of them
21 pursuant to my general question about
22 rendering a decision were provided by
23 counsel.

24 QUESTIONS BY MR. LOESER:

25 Q. And which ones did you request?

1 A. I requested the Ryan Haight Act
2 and the Council of Economic Advisors.

3 Q. Okay. And are you familiar
4 with all the documents on this list?

5 A. Yes.

6 Q. Have you read them?

7 A. I read them all.

8 Q. And what's the relevance of the
9 Chemical Handlers Manual?

10 A. Back in the early days when
11 they didn't have much -- there wasn't a lot
12 of guidance put out by the Agency, some of
13 the associations, they started talking about
14 utilizing -- and some verbal comments from, I
15 guess, some diversion investigators -- to
16 look at the -- and I think may have been in
17 2003 -- the suspicious order monitoring
18 explanations they gave in trying to develop a
19 program that would apply to controlled
20 substances.

21 Q. And so do you agree that the
22 guidance provided in the Chemical Handlers
23 Manual with regard to suspicious order
24 monitoring is important?

25 MR. DAVISON: Objection.

1 THE WITNESS: It's important,
2 but you have to be very careful with
3 suspicious order monitoring programs
4 that one size doesn't fit all. So
5 what may be appropriate for you is not
6 appropriate for me.

7 And I'm talking about if you're
8 a company and I'm a company, not you
9 as a lawyer and an expert sitting
10 here.

11 You know, and then you have to
12 look at your customer base. You have
13 a large customer base, like 10,000
14 pharmacies, whether independents or
15 chain, or you're dealing with a small
16 number of customers.

17 So to say one is more
18 appropriate than the other, to me,
19 is -- it doesn't count. It doesn't
20 mean anything.

21 QUESTIONS BY MR. LOESER:

22 Q. So did you advise your clients,
23 your DEA registrant clients, to review the
24 Chemical Handlers Manual?

25 MR. DAVISON: Objection.

1 THE WITNESS: Well, in some
2 situations we would say, you know,
3 here's what -- regulatory
4 requirements. You got to report a
5 suspicious order. Here's one method.

6 Depending on, again, who the
7 client is and their customer base,
8 maybe, yeah, you -- maybe something we
9 should consider.

10 If, depending on your client
11 base, number of clients you have, or
12 customers, I should say, we may say,
13 "No, this is not appropriate for your
14 company."

15 So it depends on a lot of
16 different things. So talking about an
17 individual thing or a general comment
18 on what the industry should do, to me,
19 is very difficult.

20 QUESTIONS BY MR. LOESER:

21 Q. But with regard to the
22 suspicious order reporting requirements, did
23 you look to the Chemical Handlers Manual as a
24 guide for clients?

25 MR. DAVISON: Objection.

1 THE WITNESS: Well, what we
2 tell clients is that they need to
3 report -- once they identify an order
4 as suspicious, once you make that
5 determination as to what's suspicious,
6 you got to report it to the DEA.

7 Again, depending on who the
8 registrant is and their customer base
9 and the type of drugs they're handling
10 and the quantities they sell, there
11 may be different types of reports that
12 we -- programs we may recommend.
13 Maybe a paper-based system will do it;
14 maybe an electronic system.

15 We go back to Mallinckrodt,
16 their systems, they had a combination
17 of things, which was appropriate.

18 MR. LOESER: I'll ask the
19 question again.

20 Can we read the question back,
21 please?

22 (Court Reporter read back
23 question.)

24 MR. DAVISON: Objection.

25 THE WITNESS: In some

1 situations, again, depending on who
2 the registrant is and their customer
3 base, the drugs they handled, number
4 of clients -- their customers that
5 they have, it may have been one that
6 we would discuss with the industry.
7 We discussed a lot of things with the
8 industry.

9 QUESTIONS BY MR. LOESER:

10 Q. It may have been one or it was
11 one?

12 A. May have been one. Depending,
13 again, as I said, who the client is and who
14 the -- what their customer base is.

15 And again, I go back to one
16 program doesn't fit the entire industry.

17 Q. Yeah, I just want to make sure
18 I understand your testimony.

19 You said it may have been one
20 of the things that you provided to your --

21 A. That we --

22 Q. -- that you provided guidance
23 to your clients.

24 But was it, in fact, something
25 that you provided to your -- some of your

1 clients as guidance?

2 A. It's possible. I don't recall
3 everything that we did, but, yeah, it's
4 possible.

5 Q. Can you give me an example of a
6 client who shouldn't follow the guidance
7 provided by the Chemical Handlers Manual?

8 MR. DAVISON: Objection.

9 QUESTIONS BY MR. LOESER:

10 Q. Let me ask it a different way.
11 Did you ever advise a client
12 not to follow the guidance provided by the
13 Chemical Handlers Manual?

14 A. No, we -- the guidance we were
15 providing was based upon your operation:
16 Here's some recommendations we would make.
17 It may have been something from the Chemical
18 Handlers since it was really the only
19 guidance that they had. It may not have
20 been.

21 In fact, we may have said, you
22 know, "This type of program utilizing your
23 customer service reps, your product managers,
24 maybe -- you know, and your compliance group
25 and your legal group and your security group

1 would be more appropriate."

2 Others we would say, "Here's
3 something that DEA has put out. It's not
4 mandated. It's something that should be
5 considered."

6 MR. LOESER: Could you read the
7 question back, please?

8 MR. DAVISON: And, Derek, we've
9 been going now an extra 20 minutes on
10 top of the break, so...

11 MR. LOESER: This is the last
12 question.

13 MR. DAVISON: Okay.

14 MR. LOESER: Well, when it's
15 answered it's the last question.

16 MR. DAVISON: Objection.

17 (Court Reporter read back
18 question.)

19 THE WITNESS: No.

20 VIDEOGRAPHER: Off the record
21 at 12:03 p.m.

22 (Off the record at 12:03 p.m.)

23 VIDEOGRAPHER: We're back on
24 the record at 12:19 p.m.

25

1 QUESTIONS BY MR. LOESER:

2 Q. Mr. Buzzeo, earlier you
3 testified in response to my questions that
4 there's an obligation to report a suspicious
5 order.

6 Do you recall that testimony?

7 A. Yes.

8 Q. How do you define a suspicious
9 order?

10 A. Well, the regulation defines it
11 as -- such as it gives quantity, pattern and
12 size of the order, frequency.

13 Q. And is that -- or can that be
14 determined with an algorithm?

15 A. Again, it depends on the
16 registrant, their customer base, the drugs,
17 for them to determine which system is best
18 for them or which -- which system is best for
19 them.

20 Q. And for certain registrants, at
21 least, that can be determined with an
22 algorithm; is that right?

23 A. Yes, that can.

24 Q. And you previously testified
25 that you worked for the legitimate industry,

1 and I think your words were that you wouldn't
2 touch diverters.

3 Do you recall that testimony?

4 A. I mentioned something to that
5 effect, that we would turn down, to my
6 knowledge, customers that would --
7 registrants that were involved in what we
8 felt was the illicit market. And I'm going
9 back a long time.

10 Q. Yeah. And, sir, how do you
11 define the legitimate industry?

12 A. They meet the DEA requirements
13 for registration.

14 Q. And what do you mean by
15 "diverters"?

16 A. Is when drugs or controlled
17 substances departs or leaks out or however,
18 what terms you want to use, from the
19 distribution chain in an illicit manner.

20 Q. So if a pharmacy provides
21 controlled substances for other than
22 legitimate medical purposes, is that a
23 pharmacy a diverter?

24 MR. DAVISON: Objection.

25 THE WITNESS: Yes. If --

1 anybody who diverts, let's say,
2 controlled substances for illicit
3 purposes would be a diverter -- would
4 be, you know, involved in diversion,
5 let's say.

6 QUESTIONS BY MR. LOESER:

7 Q. So a pain clinic that provides
8 prescriptions for other than legitimate
9 medical purposes, that would be a diverter
10 too?

11 A. Pain clinics -- pain clinics
12 were an issue that DEA looked at very
13 carefully, to my knowledge.

14 I inspected some of them for a
15 member of the industry, and some of them are
16 probably very honest, but there are a number
17 of them that were basically selling drugs.

18 Q. And you say you inspected some
19 pain clinics for a member of industry.

20 Who did you inspect pain
21 clinics on behalf of?

22 MR. DAVISON: Objection.

23 THE WITNESS: I don't recall
24 who it was. I just remember us doing
25 it. That was many years ago, when I

1 was involved in it. So that would
2 have been back probably way before --
3 probably in the '90s sometime.

4 QUESTIONS BY MR. LOESER:

5 Q. And is a dispensing physician,
6 in areas where physicians can dispense, who
7 provides prescriptions for other than
8 legitimate medical purposes a diverter?

9 MR. DAVISON: Objection.

10 THE WITNESS: For a -- based
11 upon your question, a physician who
12 provides drugs outside of
13 legitimate -- for not for legitimate
14 medical need is performing an illicit
15 activity and probably would be
16 prosecuted.

17 QUESTIONS BY MR. LOESER:

18 Q. So the answer is yes?

19 A. Yes.

20 Q. And I want to make sure I
21 understand.

22 What is the difference between
23 a company that is a diverter and one that is
24 part of a legitimate industry?

25 A. A company that's a diverter?

1 Q. Yeah.

2 A. What -- you have to rephrase
3 the question.

4 Q. Is there a difference between
5 what you're calling a company that is part of
6 the legitimate industry and a company that is
7 a diverter?

8 A. Well, I would assume if you're
9 a diverter and DEA knows it, they're going to
10 move against your registration, if it's a
11 legitimate pharmaceutical practitioner or
12 non-practitioner.

13 Q. As you understand it, is a
14 company that ships suspicious orders a
15 diverter?

16 MR. DAVISON: Objection.

17 THE WITNESS: When you talk
18 about a company -- first of all, the
19 requirement is that a company
20 reports -- once they make a
21 determination that the order is
22 suspicious, they report it to DEA, and
23 then they have to make a determination
24 of ship, don't ship.

25 The regulation really doesn't

1 say anything more than that.

2 QUESTIONS BY MR. LOESER:

3 Q. Right. I'm asking --

4 A. But I don't follow your
5 question.

6 Q. -- a slightly different
7 question.

8 You use this terminology
9 between a legitimate business and a diverter.
10 And I'm asking you if a company that ships
11 suspicious orders, is that, in your view, a
12 diverter?

13 MR. DAVISON: Objection.

14 THE WITNESS: Let's -- it's
15 possible -- let me put it this way.

16 The regulatory requirement is
17 you report suspicious orders. Okay?
18 That's regulatory requirement. And
19 you notify DEA of that.

20 If you continually ship
21 suspicious orders, that you've
22 determined is suspicious and DEA
23 determines -- if there's diversion
24 associated with that suspicious order,
25 then you are supplying drugs into

1 the -- outside the regulatory
2 requirements, outside of the
3 distribution chain, outside that
4 registration chain.

5 So it ties into -- you could
6 have an order pended that could be,
7 based upon your criteria, suspicious,
8 but when you do your investigation,
9 it's not suspicious. So if it's just
10 based upon your program, then it's
11 very difficult to answer that
12 question.

13 QUESTIONS BY MR. LOESER:

14 Q. Let me try --

15 A. But if you know -- if you know
16 that the drug is being diverted, then you
17 have somebody who is supplying the illicit
18 market.

19 Q. Let me try and get an answer.
20 If a company ships suspicious
21 orders, is that company a diverter?

22 MR. DAVISON: Objection. Asked
23 and answered.

24 QUESTIONS BY MR. LOESER:

25 Q. Actually ships a suspicious

1 order, is that company a diverter?

2 MR. DAVISON: Objection. Asked
3 and answered.

4 THE WITNESS: If the drug -- if
5 the drug is diverted into the illicit
6 market and they're aware of that,
7 that's a -- but you could have -- I'm
8 trying to say is that you can have an
9 order that your system -- and based
10 upon your cri -- you say, "this order
11 is suspicious." It turns out maybe
12 it's not suspicious.

13 So unless there's something
14 connected with that, like diversion or
15 something, you're supplying the
16 illicit market, then you shouldn't
17 have a registration.

18 QUESTIONS BY MR. LOESER:

19 Q. Okay. So if the order is
20 suspicious, not if it might be, not if it's
21 later determined to be, but if an order is
22 suspicious and a company ships that order, is
23 the company a diverter?

24 MR. DAVISON: Objection. Asked
25 and answered.

1 THE WITNESS: And is diversion
2 associated with it? Yes.

3 QUESTIONS BY MR. LOESER:

4 Q. Is a company that has its
5 license to distribute controlled substances
6 revoked by the DEA, in your view, a diverter?

7 MR. DAVISON: Objection.

8 THE WITNESS: I don't have
9 enough details to even answer that
10 question.

11 QUESTIONS BY MR. LOESER:

12 Q. If the DEA revokes a company's
13 license to distribute controlled substances
14 because the company has not utilized
15 appropriate controls against diversion, is
16 that company a diverter?

17 MR. DAVISON: Objection.

18 THE WITNESS: Again, I need to
19 know the details.

20 Is it just a recordkeeping
21 issue or a security issue, you know,
22 physical security?

23 Was it they didn't have proper
24 records but there was no actual no
25 evidence of diversion?

1 I don't know. I'd have to know
2 the details.

3 QUESTIONS BY MR. LOESER:

4 Q. And again, I'm trying to
5 understand your terminology. You used this
6 word "diverter."

7 If the DEA revokes a company's
8 license to distribute controlled substances
9 because that company allowed for
10 prescriptions without legitimate medical
11 purposes, would you consider that company a
12 diverter?

13 A. If a registrant distributed
14 controls drugs without -- not pursuant to a
15 prescription, then they're actually dealing
16 in controlled substances and probably would
17 be a criminal charge.

18 Q. What about if it's pursuant to
19 a prescription but it's not for a legitimate
20 medical purpose?

21 A. If a registrant distributes
22 controlled substances either pursuant to a
23 prescription or not and it's not for
24 legitimate medical purposes, there could be a
25 violation of the CSA, again, depending on all

1 the details.

2 And the same way with the
3 doctor. Did the physician prescribe not for
4 legitimate medical need. So does that
5 physician -- there's a corresponding
6 liability on the pharmacist because -- that's
7 it.

8 Q. And, therefore, using the
9 terminology that you used, you would label
10 those entities diverters in those instances?

11 MR. DAVISON: Objection.

12 THE WITNESS: Well, the drugs
13 that leaked out of legitimate medical
14 distribution.

15 QUESTIONS BY MR. LOESER:

16 Q. Mr. Buzzeo, is this the first
17 time you've served as an expert consultant in
18 litigation?

19 A. No.

20 Q. How many times have you served
21 as an expert?

22 A. I don't recall the number, but
23 it was a few.

24 Q. And more than ten?

25 A. It's hard to say. I don't

1 think it would be more than ten, no.

2 Q. Do you recall any of the
3 specific matters for which you've previously
4 served as an expert?

5 A. Mainly registration issues.

6 Q. In litigation?

7 A. No, in front of an
8 administrative law judge.

9 Q. Okay. And do you recall
10 anything specific -- do you recall what those
11 matters were, who you were an expert on
12 behalf of?

13 A. The registrant -- or the
14 company making application for registration.

15 Q. Do you recall the name of the
16 company?

17 A. No.

18 Q. And --

19 A. In 53 years, it's hard to
20 recall the names of a lot of --

21 Q. Do you recall any other times
22 that you served as an expert in litigation?

23 A. There was one that was for --
24 and I don't recall who it was. It was a
25 pharmacy. Had to do with I think security or

1 something. One of the pharmacists was
2 stealing drugs.

3 Q. Do you recall what pharmacy
4 that was?

5 A. No, I don't.

6 Q. Are there any other matters
7 that you recall?

8 A. No, that's about it.

9 And of course when I was with
10 the Agency, criminal trials.

11 Q. Right.

12 And do you recall what law
13 firms retained you in those matters?

14 A. God, no, I don't.

15 Q. Do you recall any other details
16 at all about either of those matters?

17 A. No. Registration -- and that
18 had to do with obtaining a registration.
19 But, no, that's about all that I can recall.

20 Q. And in those two matters, were
21 you an expert for the plaintiff or the
22 defendant?

23 A. In one it was with the --
24 expert for the registrant, and the others
25 were as an expert for either maintaining a

1 registration or obtaining a new registration.

2 It was not a civil issue. It
3 was not a criminal issue.

4 Q. Okay. And you don't recall
5 the -- who the registrant was in either of
6 those?

7 A. I don't. Probably had to do
8 with a bulk manufacturer or somebody trying
9 to get into that business.

10 Q. And do you recall when you last
11 served as an expert in any litigation?

12 A. Probably would have been in
13 early 2000, late 2000. Maybe right after
14 2000 -- you know, 2001, sometime in that time
15 frame.

16 Q. And you don't have any records
17 that would --

18 A. No. God, no.

19 Q. Have you ever testified under
20 oath in any capacity?

21 A. Oh, yes.

22 Q. After you left the DEA?

23 A. Some of these trials.

24 Q. And were there trials in both
25 of those --

1 A. One was a trial. The others
2 were administrative hearings in front of a
3 law judge.

4 Q. Okay. You mentioned two.
5 Do you think there might have
6 been more than two?

7 A. Of the registration hearings?

8 Q. Anytime you served as an
9 expert.

10 A. Yes. Yes. There was -- here
11 was -- I don't recall the exact number, but I
12 know it was more than two.

13 Q. And do you recall how many of
14 those matters went to trial?

15 A. The registration ones? I don't
16 think any of them went to trial.

17 Q. Were there administrative
18 proceedings?

19 A. It was an administrative law
20 judge, and then they -- the law judge would
21 publish a finding in the Federal Register.

22 Q. Okay. So if we searched on
23 your name in the Federal Register, we should
24 be able to find it?

25 A. Sure, try that.

1 Q. Have you ever offered testimony
2 before a grand jury?

3 A. No.

4 Q. And other than the
5 administrative proceeding you mentioned, any
6 testimony before any federal agencies after
7 you left DEA?

8 A. I don't recall the facts, but
9 it was before FDA at a -- they were gathering
10 evidence for some regulation or something. I
11 don't remember the details. It was a while
12 ago. But that was the only one.

13 Q. Was that something to do with
14 controlled substances?

15 A. It would have had something to
16 do with controlled substances.

17 Q. Do you have any recollection --

18 A. No.

19 Q. -- of what?

20 A. (Witness shakes head.)

21 Q. Do you know the year that that
22 occurred?

23 A. No.

24 Q. A range of possible years?

25 A. It was the only thing I was

1 involved in. Probably in the 2000 time frame
2 or late '90s maybe.

3 Q. Do you recall why you were
4 involved in that?

5 A. Probably had do with a control
6 issue or could have been a recordkeeping
7 issue or something that we felt that should
8 be added to it, but the details I don't
9 recall. But I know there was that one, but
10 that's about it.

11 And then criminal trials, which
12 I've told you. When I was with the Agency,
13 there was a number of criminal trials.

14 Q. Has your -- in the matters
15 that -- I understand you don't recall very
16 well, but where you have been an expert, has
17 there been any challenge to your ability to
18 serve as an expert?

19 A. None whatsoever.

20 Q. What about prior litigation
21 experience, have you ever been a litigant in
22 a lawsuit?

23 A. No.

24 Q. Never been a plaintiff?

25 A. No.

1 Q. Never been a defendant?

2 A. No.

3 Q. So we went through your CV in
4 detail, and fair to say that from 1991
5 through 2015 you provided consulting services
6 to DEA registrants specifically pertaining to
7 compliance with the Controlled Substances Act
8 and the implementing regulations of the CSA,
9 correct?

10 A. And the PDMA.

11 Q. And the PDMA.

12 And since leaving BuzzeoPDMA,
13 you have continued to consult DEA registrants
14 on CSA compliance?

15 A. Since I left the company?

16 No, the only discussions I've
17 had is with some law firms.

18 Q. Okay. If we could look at your
19 report, if you could turn to paragraph 19.

20 In paragraph 19, in describing
21 your expert report, you state, "I have
22 reviewed these reports based on my years of
23 industry experience focusing on the
24 Controlled Substances Act and its
25 implementing regulations."

1 Did I read that correctly?

2 A. Yes.

3 Q. And then in the following
4 paragraph, paragraph 20, you state that
5 you've been asked by counsel for Mallinckrodt
6 to review Mallinckrodt's suspicious order
7 monitoring program and anti-diversion
8 program, "consistent with my years of
9 industry experience auditing manufacturers
10 and distributors of controlled substances."

11 Did I read that correctly?

12 A. Correct. Yes.

13 Q. And then in paragraph 21 you
14 state at the end of the paragraph, "I have
15 also relied on my more than 50 years of
16 experience in the industry, including my
17 22 years working for the DEA."

18 Is that right?

19 A. Correct.

20 Q. And so you would agree that
21 your experience auditing and providing
22 guidance to other DEA registrants, including
23 manufacturers, distributors and chain
24 pharmacies, informs your opinions in this
25 case?

1 A. Yes.

2 Q. And in reaching the conclusions
3 that you indicate in your report, it's fair
4 to say that you rely on your prior experience
5 auditing and providing guidance to DEA
6 registrants?

7 A. And the regulations.

8 Q. So that's correct?

9 A. And my time with DEA.

10 Q. Okay.

11 A. And probably the state
12 somewhat.

13 Q. And so the answer is, yes, you
14 do --

15 A. Yes.

16 Q. Yes, you rely on your prior
17 experience, as you've just described it, in
18 reaching the opinions that you indicated --

19 A. And the other thing --

20 MR. DAVISON: Let him finish.

21 QUESTIONS BY MR. LOESER:

22 Q. -- in reaching the opinions
23 that you've stated in your report?

24 A. And the regulations and
25 experience I have in those regulations.

1 Q. Okay. So again, the answer is
2 yes. And in addition to what I've indicated,
3 you've added you've also relied on the
4 regulations --

5 A. Correct.

6 Q. -- and your experience with the
7 regulations?

8 A. Correct.

9 Q. If you look at Section 4 of
10 your report, paragraph 28, you state, "During
11 my 50 years of experience in the industry, I
12 have conducted dozens of audits of compliant
13 systems, anti-diversion efforts and
14 suspicious order monitoring programs for DEA
15 registrants. I have audited and evaluated
16 suspicious order monitoring programs and
17 anti-diversion programs of a number of
18 controlled substances, pharmaceutical
19 manufacturers. I have assisted numerous
20 registrants, including controlled substances
21 manufacturers, in implementing suspicious
22 order monitoring programs and anti-diversion
23 programs."

24 Did I read that correctly?

25 A. Yes.

1 Q. And, sir, could you please read
2 the first sentence of paragraph 29?

3 A. "In preparing this report, I
4 evaluated Mallinckrodt's suspicious order
5 monitoring program and anti-diversion efforts
6 in the same way as I have in dozens of audits
7 and evaluations of controlled substance
8 registrants in my 50 years of experience.
9 Consistent" -- first sentence.

10 Q. Okay. Thank you.
11 And so you were asked by
12 Mallinckrodt counsel to give an opinion about
13 Mallinckrodt's compliance with the CEA and
14 the implementing regulations of the CSA,
15 correct?

16 A. Yes.

17 Q. And in order to provide this
18 opinion, you followed the same procedures you
19 follow when a DEA registrant hires you to
20 perform an audit or evaluation, correct?

21 A. Yes.

22 Q. So your evaluation of
23 Mallinckrodt for this case was done in the
24 same way, as you say in your report, as your
25 prior audits of DEA registrants, correct?

1 A. Yes.

2 Q. Sir, would you consider
3 yourself to be an expert in compliance with
4 the Controlled Substances Act?

5 A. Yes.

6 Q. What is the purpose of the
7 Controlled Substances Act?

8 MR. DAVISON: Objection.

9 THE WITNESS: To implement a
10 program or a requirement that sets up
11 a chain of various registrants to
12 handle controlled substances.

13 And in order to put that in
14 place, you got registration -- there
15 are various other requirements of
16 the -- of the CSA in implementing
17 regulations.

18 QUESTIONS BY MR. LOESER:

19 Q. And what is -- what are the --
20 what is the purpose of the implementing
21 regulations of the CSA?

22 MR. DAVISON: Objection.

23 THE WITNESS: To prevent
24 diversion, abuse of controlled
25 substances.

1 QUESTIONS BY MR. LOESER:

2 Q. And how do they do that?

3 A. Through the various
4 requirements that the regulations and any
5 guidance provided by DEA.

6 So you have a registration, so
7 you're required to get a registration. In
8 order to get a registration, you have to have
9 the appropriate security in place.

10 So once you get the
11 registration, then you have certain
12 recordkeeping requirements, reporting
13 requirements, that try to prevent that.
14 Prescription requirements.

15 Q. And reporting requirements?

16 A. Yeah.

17 Q. And if one wanted to understand
18 the purpose and the requirements imposed by
19 the CSA, where would one look?

20 A. Proposed by the CSA?

21 Q. Yeah. If you wanted to fully
22 understand what the requirements are of the
23 CSA, what would one look at?

24 A. You'd look at the act and the
25 implementing regulations.

1 Q. And what about regulatory
2 guidance; would you look at that as well?

3 A. Yeah, there's -- there's --
4 DEA, I guess, on SOM, in '06 and '07, put out
5 three guidance letters.

6 Q. And specifically with regard to
7 manufacturers, what obligations does the CSA
8 impose on them?

9 A. Well --

10 MR. DAVISON: Objection.

11 THE WITNESS: -- the
12 practitioner level, the -- a good --
13 both the practitioner and the
14 non-practitioner level have the
15 regulations that they have to put in
16 place.

17 Manufacturers and distributors,
18 or the non-practitioners, are a little
19 different than the practitioner level.
20 One of them would be prescriptions.

21 You have to be a physician to
22 prescribe. You have to be a pharmacy
23 to dispense, unless you're in a state
24 that has dispensing physicians.

25 But manufacturers and

1 distributors, if you involve the
2 quota, the manufacturer has to obtain
3 from DEA what they're allowed to
4 manufacture to meet their distribution
5 requirements.

6 You know, so you have different
7 requirements at each -- at each level.

8 QUESTIONS BY MR. LOESER:

9 Q. What are the reporting
10 requirements that apply to an opioid
11 manufacturer?

12 A. Manufacturer? ARCOS, loss and
13 theft, suspicious order monitoring.
14 Depending on what type of manufacturer, they
15 may have some UN reporting requirements, the
16 data that they have to provide DEA for DEA to
17 send in to the UN.

18 Those are some of the -- then
19 there's labeling issues, physical security,
20 things like that.

21 Q. And generally speaking, and
22 we'll get into more specifics later, but what
23 are the obligations the CSA imposes on opioid
24 distributors?

25 A. I'm sorry.

1 Q. What are the obligations the
2 Controlled Substances Act imposes on
3 distributors?

4 A. Distributors?

5 MS. DICIURCIO: Objection.

6 Outside the scope.

7 MR. DAVISON: You can answer.

8 QUESTIONS BY MR. LOESER:

9 Q. Outside the room.

10 A. For distributors, it would be
11 security. It would be reporting requirements
12 similar to what the manufacturers have. So
13 you'd have ARCOS, loss and theft, SOMs,
14 recordkeeping requirements, which is similar.
15 Or if you're a manufacturer, of course you've
16 got batch records and stuff like that.
17 Distribution records.

18 And there's other things in
19 there that -- I didn't go into everything,
20 but that's basically it.

21 Q. And what would you say are the
22 differences between the CSA obligations
23 imposed on manufacturers and those imposed on
24 distributors?

25 A. The difference?

1 Q. Yeah.

2 A. Well, the manufacturing, you're
3 getting into where you're actually
4 manufacturing something, so they're going to
5 have a whole slew of recordkeeping, batch
6 records, and FDA plays a role. Lab analysis.
7 They may do some drug research. Depending,
8 they may require other registrations.

9 You get into a distributor,
10 it's the distributor registration. They
11 can't repackaging or manufacture, no
12 manufacturing activities. And I'm not
13 talking about putting a bottle in a box and
14 shipping it. They have security
15 requirements, receiving records, distribution
16 records.

17 And, of course, I said
18 reporting requirements. That's the loss and
19 theft, registration, verification, and the
20 SOM.

21 So basically the same, with
22 different exceptions, requirements, that
23 manufacturers have.

24 Q. And are the reporting
25 requirements the same for distributors and

1 manufacturers?

2 A. Again, depending -- if you're
3 talking about ARCOS, they both have ARCOS.
4 Depending on the type of drugs they handle,
5 yes, they would be the same if they're
6 handling the same drugs, which is Schedule II
7 and Schedule III narcotics, Schedule I and
8 Schedule II and Schedule III narcotics.

9 If you're talking about SOM,
10 yes, it's a distribution requirement.

11 And loss and theft, yes. The
12 manufacturer may have some other areas where
13 they have differences in loss and theft.

14 And in selecting a common
15 contract carrier that provides adequate
16 security, yes.

17 And verification --
18 registration verification, yes, they would be
19 the same.

20 Q. Sir, do you believe it's
21 important for a DEA registrant to have
22 standard operating procedures for its
23 anti-diversion and suspicious order
24 monitoring system?

25 MR. DAVISON: Objection.

1 THE WITNESS: Well, there's no
2 requirement to have SOPs in the CSA or
3 the implementing regulations
4 whatsoever.

5 FDA is the one who has
6 requirements, like in the PDMA that
7 handles samples, stuff like that.

8 But does it make it easier
9 or -- that a company have something,
10 either you want to call it an SOP or a
11 memorandum or something and they train
12 their employees? That could be
13 acceptable, but you should have
14 something.

15 QUESTIONS BY MR. LOESER:

16 Q. And so you generally advise
17 your DEA registrant clients to have SOPs or
18 something like it with regard to its
19 suspicious order monitoring and
20 anti-diversion practices?

21 MR. DAVISON: Objection.

22 THE WITNESS: The short answer
23 is yes, but we'll advise it that
24 security, access, how do you handle
25 the visitors, how do you handle DEA

1 audit, SOM, something, either -- like
2 I said, SOPs or, as you mentioned, or
3 other documents, training procedures.

4 So there's a number of things
5 that we would recommend.

6 QUESTIONS BY MR. LOESER:

7 Q. If a DEA registrant is aware of
8 an unusual pattern of geographic distribution
9 of their product to pharmacies, pain clinics
10 and physicians, does the CSA require the
11 registrant to report these orders to the DEA?

12 MR. DAVISON: Objection.

13 THE WITNESS: Again, it depends
14 on the type of customers you have. If
15 it's a manufacturer that only
16 services, let's say, wholesalers,
17 well, they may not have that
18 information.

19 A distributor whose customer
20 base is pharmacies, they may have that
21 information.

22 QUESTIONS BY MR. LOESER:

23 Q. So let me ask you again.

24 A. Okay.

25 Q. And I'm not asking what

1 information they have. I'm asking if a DEA
2 registrant is actually aware of an unusual
3 pattern of geographic distribution of their
4 product to pharmacies, pain clinics and
5 physicians, does the CSA require the
6 registrant to report these orders to the DEA?

7 MR. DAVISON: Objection.

8 THE WITNESS: The regulation
9 requires you to report suspicious
10 orders. If your customer base is what
11 you mentioned, yes, you would have.

12 Now, if you have -- if you're
13 aware of diversion or something, you
14 read about something in the newspaper
15 or whatever way you get the
16 information -- like Mallinckrodt
17 reacted to that and addressed the
18 issue in Florida, Nevada, Ohio, when
19 they found out about it.

20 Now, when you talk about the
21 CSA, the requirement is you're a
22 registrant, you have requirements.
23 Next registrant, you have
24 requirements.

25 As you go down to the

1 distribution line, everybody has a
2 requirement. If you possess that
3 product, you have your requirement to
4 meet those sections of the
5 regulations.

6 QUESTIONS BY MR. LOESER:

7 Q. If a DEA registrant is aware
8 that specific pharmacies, pain clinics and
9 physicians are purchasing unusual amounts in
10 increasing frequency from multiple
11 distributors, should the registrant report
12 these orders to the DEA?

13 MR. DAVISON: Objection.

14 THE WITNESS: If you make a
15 determination, the registrant makes a
16 determination, that order is
17 suspicious after they do their due
18 diligence, the answer...

19 QUESTIONS BY MR. LOESER:

20 Q. The answer is?

21 A. Did you have another part of
22 that question?

23 No, I'm just asking because you
24 started to say something. I don't --

25 Q. Yeah, I can ask the question --

1 A. If it wasn't directed to me,
2 then I'll back up.

3 Just repeat the question,
4 please.

5 Q. Yeah. If a DEA registrant is
6 aware that specific pharmacies, pain clinics
7 and physicians are purchasing unusual amounts
8 in increasing frequency from multiple
9 distributors, should the registrant report
10 these orders to the DEA?

11 MR. DAVISON: Objection.

12 THE WITNESS: If you're -- if
13 you -- if an order, let's say, pends
14 because of the criteria you just gave,
15 and you do your due diligence, as part
16 of that due diligence is you go out --
17 you're a distributor, let's say. You
18 go out and look or whatever, and it
19 turns out the order is suspicious, you
20 report it to DEA.

21 QUESTIONS BY MR. LOESER:

22 Q. What if the registrant flags
23 the order as suspicious because its algorithm
24 indicates that the order is an unusual amount
25 in increasing frequency from multiple

1 distributors, at that point should the
2 registrant report that to the DEA?

3 MR. DAVISON: Objection.

4 THE WITNESS: Well, in that
5 situation, if your order pends, for
6 whatever reason it is, you have to
7 make a determination if it's
8 suspicious or not. Just because
9 something pends doesn't make it
10 suspicious.

11 I'll give you an example. You
12 set up an algorithm that says anything
13 over 20,000 -- and I'm just making up
14 a number -- is going to pend. Well,
15 just because it pends at 20,000
16 doesn't make it suspicious.

17 You go out and you look at who
18 the customer is. Is the customer a
19 hospital that's using large quantities
20 of opioids and they're purchasing
21 30,000, does that make it suspicious?
22 Not necessarily.

23 You may have a customer that's
24 only purchasing a thousand, which is
25 way under. That may be suspicious if

1 your system kicked it out.

2 So it's hard to make a definite
3 statement.

4 QUESTIONS BY MR. LOESER:

5 Q. Let me try and make sure I get
6 you a question that you understand.

7 A. Okay.

8 Q. If the DEA registrant
9 determines that an order or series of orders
10 are in unusual amounts, they are in
11 increasing frequency and they're from
12 multiple distributors, is that a circumstance
13 that you would describe as suspicious?

14 MR. DAVISON: Objection.

15 THE WITNESS: If you make -- if
16 you look at that and make a
17 determination that it is suspicious,
18 you've looked at everything that you
19 should be looking at, then you report
20 it to DEA.

21 QUESTIONS BY MR. LOESER:

22 Q. Okay. I want to better
23 understand the kinds of audits that you do
24 since you've testified that you took the same
25 approach here with your task for

1 Mallinckrodt.

2 First of all, how does a DEA
3 registrant find out about you and hire you?

4 A. Website. Well, first of all,
5 I'm not --

6 Q. When you were more active.

7 A. Okay. Website, word of mouth,
8 recommendations from lawyers, recommendations
9 from US Attorneys, recommendations from other
10 customers, I've said that, association
11 meetings we go to, presentations we give in
12 front of associations.

13 A number of ways.

14 Q. And when you're hired by a
15 company to perform an audit of their CSA
16 compliance, what do you do to investigate?

17 A. What do we -- I didn't get
18 that. What do we --

19 Q. When you're hired to perform a
20 CSA audit, what do you do to investigate?

21 A. To investigate?

22 Q. Yeah.

23 A. Well, it's really an
24 inspection. It's a regulatory review.

25 Now, depending on what the

1 client is actually asking for, we would go on
2 site and we review records. We may do an
3 accountability, you know, look at internal
4 documentation, look at how they receive
5 product, how they ship product, how they
6 select the common contract carrier, if
7 they're a manufacturer or a distributor, if
8 it's a pharmacy or a chain, whatever it is,
9 independent chain, go in and look at how they
10 handle controlled drugs and prescriptions and
11 stuff like that.

12 Due diligence, we're looking at
13 are there any regulatory issues -- we don't
14 look at anything financial -- any regulatory
15 issues. Are they meeting the regulatory
16 issues. If they are -- regulatory
17 requirements -- you know, you can go ahead,
18 and our recommendation would be, yeah, we
19 haven't found any.

20 So it really depends on the
21 situation, who is requesting it and what are
22 they actually requesting.

23 Q. And do you interview people
24 that work for the company?

25 A. If we're on site, yeah.

1 Q. And are you typically on site
2 when you're auditing a company's compliance
3 with the CSA?

4 A. No, we've done some paper
5 reviews off site.

6 Q. Okay. What's the norm for your
7 practice?

8 A. It really depends on the
9 client. Some want just a paper review, and
10 we'll ask for the documents. Some will ask
11 us to go on site and look at various
12 situations. Especially if they're asking you
13 to look at the physical security, if they
14 want the physical security looked at, so we
15 send our security expert.

16 Q. And what percentage of the time
17 would you say that there's an on-site review?

18 A. Oh, I don't recall, but there
19 was -- we had a number of on-sites and a
20 number of paper reviews.

21 Q. And when you're not on site, do
22 you ever interview people?

23 A. We may, may not. Depends on
24 what they're asking us to do.

25 Q. And how do you choose who to

1 interview?

2 A. Excuse me?

3 Q. How do you choose who to
4 interview?

5 A. Depending on what we're being
6 asked to do. If we determine -- if we're
7 doing an off-site review, let's say a paper
8 review, we may or may not. It really depends
9 on what we're looking at.

10 If we have a question -- let's
11 say they want us to look at their receiving
12 and distribution records, they send us
13 examples.

14 If we have a question on the
15 record, like, is this really a distribution
16 record?

17 Well, yeah.

18 Are you sure it's really a
19 distribution record, because it doesn't have
20 the customer's registration number on it.

21 So it's things like that we may
22 go back and have a discussion.

23 Q. What about when you're
24 reviewing a suspicious order monitoring
25 program and anti-diversion controls, is that

1 typically on site?

2 A. Yeah. A lot of them are on
3 site; some can be off site.

4 Q. And then they're on site, how
5 do you determine who to interview?

6 A. Depending on who's involved in
7 the program.

8 Q. Okay. So you look for all the
9 people that are involved and you interview
10 them?

11 MR. DAVISON: Objection.

12 THE WITNESS: Yeah, if it's
13 required to be on site.

14 QUESTIONS BY MR. LOESER:

15 Q. And what are the tools that you
16 use to assess compliance?

17 A. Compliance?

18 MR. DAVISON: Objection.

19 QUESTIONS BY MR. LOESER:

20 Q. Yeah, with the CSA.

21 And specifically -- let me be
22 clear -- compliance with the reporting
23 requirements, the SOM program and the
24 anti-diversion.

25 A. Okay. Compliance people,

1 security, legal -- and not necessarily in
2 this order -- probably sales and operations,
3 product managers. Depending on the review,
4 we may touch all of them, touch some of them.
5 HR, hiring processes, hiring procedures.

6 Q. And what are the tools that you
7 use to assess compliance?

8 MR. DAVISON: Objection.

9 THE WITNESS: Tools?

10 QUESTIONS BY MR. LOESER:

11 Q. Do you have a set of standards
12 that you apply? Are there a set of metrics
13 that you utilize when you're evaluating a SOM
14 program or anti-diversion efforts?

15 A. If you're talking about that,
16 then we'll look at it based upon the
17 regulations, we'll base it upon industry
18 standards, and we'll base it upon -- we may
19 take a -- one of our people with us, if they
20 want us to look at a SOMs program, which
21 could be a statistician. It could be an
22 expert in com -- if it's a computer program,
23 a computer service, you know, how to handle
24 the computer. It really depends on what
25 we're being asked to do.

1 Q. Well, let's say you're being
2 asked to evaluate whether a SOM program
3 complies with regulations and the CSA.

4 A. Well, it's not necessary that
5 you have a system, okay? So --

6 Q. Let's say a company has a
7 system, and they're hiring you and BuzzeoPDMA
8 to audit that system. Are there factors or
9 standards that you utilize when doing that?

10 MR. DAVISON: Objection.

11 THE WITNESS: Well, we'll
12 look -- well, again, depending on the
13 client and the process they have in
14 place will determine how we look at
15 it.

16 Are we looking at it just based
17 upon records and how that process
18 works? Are they asking us to go in
19 depth into, if they have electronic
20 system, how that system works? We'll
21 look at it that way.

22 But it really depends on what
23 we're being asked to do. Because,
24 like I said, depending on your client
25 base will determine what kind of

1 system you have in place.

2 So if you have a large client
3 base, that is one determination you
4 use in which you -- how you're looking
5 at it. If you have a very small
6 client base, that will influence how
7 you look at it.

8 QUESTIONS BY MR. LOESER:

9 Q. Well, let me try and clarify.
10 If you've been asked by a major
11 pharmaceutical manufacturer to evaluate its
12 SOM program and anti-diversion efforts, are
13 there metrics or tools that you utilize to
14 assess compliance?

15 MR. DAVISON: Objection.

16 THE WITNESS: The regulations
17 and the experience that either I have
18 or, when I had the company, the people
19 have.

20 QUESTIONS BY MR. LOESER:

21 Q. And do you have any kind of
22 checklist or standard procedures that you
23 would utilize when performing an audit like
24 that?

25 A. We had checklists.

1 Q. Okay. And what was on the
2 checklist?

3 A. A number of questions of how do
4 you receive physical security questions,
5 examples of receiving records, what's the
6 distribution record, things like that.
7 Prescriptions, how many prescriptions. You
8 know, if it's a pharmacy, how much of your
9 business is noncontrolled, controlled, how
10 much is cash, how much is check or insurance
11 plan. Depending on who the registrant is.

12 Q. What was on your checklist for
13 reporting requirements?

14 A. That would be in the security
15 section. Do you have an SOM program.

16 Q. And what would you look for
17 with regard to the SOM program?

18 A. Again, we'd -- first thing we'd
19 look at is your client -- your customer base,
20 and then we'd look at -- if it was a computer
21 program and they wanted us to look at that
22 point, then we'd bring in one of our computer
23 people.

24 If it was just how the process
25 works, how the employees are involved in it,

1 then that's handled differently, and that's
2 really a paper review, a process review.

3 So it really depends. Again,
4 it gets back to what you've been hired to do
5 and what's your customer base.

6 Q. Did you make any --

7 A. I've seen systems -- let me say
8 this. I've seen systems that had -- where
9 companies had very small -- has a very small
10 number of customer base. Everything's done
11 on paper.

12 Q. And did you make any effort to
13 measure the effectiveness of a suspicious
14 order monitoring program?

15 MR. DAVISON: Objection.

16 THE WITNESS: Again, depending
17 on what we were asked to do, we would
18 look at the process, you know, how do
19 you determine -- how do you pend an
20 order. Whether it's paper-based
21 system or electronic, how do you pend
22 that order, and then what do you do if
23 it pends.

24 QUESTIONS BY MR. LOESER:

25 Q. And what would you evaluate

1 about that? What were you looking for?

2 A. Looking for is if they -- did
3 the determination of what's suspicious/not
4 suspicious work? And --

5 Q. How did you determine that?

6 A. Well, it's -- again, it
7 depends. I was more in the regulatory area,
8 and I would look for the process, an order --
9 when an order comes in, what happens to that
10 order? How does it go through the process?
11 How do people look at it from a suspicious
12 order monitoring program? Who looks at it
13 first? Does your customer service reps look
14 at it first? Do your product managers look
15 at it? Does security get involved in it?
16 Does legal get involved in the process? Does
17 compliance get involved in the process?

18 These are -- these are not
19 simple questions. They're detailed
20 questions. You have to know the details, the
21 customer base, before -- in order to render
22 that decision.

23 Q. Let me ask you this. In all of
24 your years of auditing suspicious order
25 monitoring programs, did you ever see one

1 that you thought was inadequate?

2 A. Inadequate?

3 Q. Yeah.

4 MR. DAVISON: Objection.

5 THE WITNESS: It's possible. I
6 would -- I think possibly.

7 QUESTIONS BY MR. LOESER:

8 Q. And give me an example of what
9 would be an inadequate suspicious order
10 monitoring program.

11 MR. DAVISON: Objection.

12 THE WITNESS: Again, I said
13 it's possible because I don't recall
14 actual investigations that I've done
15 or was involved in.

16 QUESTIONS BY MR. LOESER:

17 Q. You don't recall a single --
18 the details of a single suspicious order
19 monitoring program that was inadequate?

20 MR. DAVISON: Objection.

21 THE WITNESS: No, because,
22 again, we wouldn't work for a company
23 that was really involved in diversion.
24 So a lot of the systems we looked at,
25 we may recommend something that's not

1 a regulatory requirement but something
2 you should look at and consider.

3 Or if there are guidance
4 letters that came out, we may -- as we
5 talked about earlier, we may recommend
6 something else that they should add to
7 their system.

8 Or we may say, you know, you
9 have to involve security in the
10 process of determining whether
11 security or not security.

12 So it's things like that.

13 QUESTIONS BY MR. LOESER:

14 Q. Did you ever get involved in an
15 audit where you determined that diversion was
16 actually occurring based upon the flawed
17 suspicious order monitoring program that the
18 registrant utilized?

19 MR. DAVISON: Objection.

20 THE WITNESS: Not suspicious
21 order. Most of them were involved in
22 employee theft and how to prevent
23 employee theft. How were they
24 doctoring the records.

25 And I'm talking about the

1 distribution chain, not just the
2 manufacturer, is where -- how can I
3 prevent -- I've had some theft, how do
4 I prevent it. I'm a bulk manufacturer
5 and somebody is stealing some of my
6 product. You know, it's things like
7 that we'd look at. Or I had an
8 extraordinary loss. Is that diversion
9 or was it just a manufacturing loss
10 because the filter broke?

11 At the practitioner level,
12 hospital says, you know, we had a
13 nurse or a PA or a physician
14 apparently is maybe a drug user, how
15 do we prevent that from happening
16 again.

17 At the pharmacy level, same
18 situation.

19 So those are the type of losses
20 we were involved in.

21 QUESTIONS BY MR. LOESER:

22 Q. So let me ask you this --

23 A. And we were looking at it from,
24 how do I prevent this from happening again.
25 How do I prevent somebody from doctoring a

1 record in the hospital so they don't divert
2 product and give it to themselves instead of
3 giving it to the patient.

4 At a distributor level, the
5 distributor wants to know, I want to prevent
6 diversion of my product. How do I do that?

7 Or this is -- I shouldn't say
8 that. I put this in place. How do I
9 prevent -- you know, do I -- there's ways --
10 should I upgrade it. Because you've looked
11 at a lot of industry. And the same way with
12 the manufacturer.

13 That was mainly the losses that
14 we were involved.

15 MR. DAVISON: And, Derek,
16 whenever is a good point, it's almost
17 1. We could take a break.

18 MR. LOESER: Okay. A couple
19 more questions.

20 QUESTIONS BY MR. LOESER:

21 Q. Mr. Buzzeo, would you agree
22 that every time you completed an audit or
23 prepared a recommendation or a report for a
24 DEA registrant client, it was done with the
25 view of ensuring that the registrant would

1 be, in your view, in full compliance with the
2 CSA?

3 MR. DAVISON: Objection.

4 THE WITNESS: As I mentioned
5 earlier, when we looked at a -- we did
6 a review of a registrant, we were
7 looking at it from you meet the
8 requirements, here's what we suggest.
9 You maybe enhance it. Here's some
10 recommendations we would make. That's
11 what we look at.

12 QUESTIONS BY MR. LOESER:

13 Q. And, sir, when you would give
14 your registrant client a report or make a
15 recommendation, was that done for the purpose
16 of ensuring that if the registrant followed
17 your recommendation, they would be in full
18 compliance with the CSA?

19 MR. DAVISON: Objection.

20 THE WITNESS: At that point in
21 time.

22 QUESTIONS BY MR. LOESER:

23 Q. Yes.

24 At that point in time, yes?

25 A. Yes.

1 Q. Okay.

2 A. Let me back up on that.

3 I want to clarify -- can I
4 clarify a statement?

5 Q. You know, you'll have a chance
6 when -- if your counsel wants to ask you to
7 clarify it.

8 A. Okay. Go ahead.

9 MR. DAVISON: Take a break.

10 VIDEOGRAPHER: Off the record
11 at 1:03 p.m.

12 (Off the record at 1:03 p.m.)

13 VIDEOGRAPHER: We're back on
14 the record at 1:54 p.m.

15 QUESTIONS BY MR. LOESER:

16 Q. Mr. Buzzeo, when you were with
17 BuzzeoPDMA, was it the general practice to
18 provide your DEA registrant clients with a
19 written report following an audit or an
20 evaluation that you did of their CSA
21 compliance?

22 A. If they requested a report or
23 wanted a report, again, depending on how we
24 were retained, yes.

25 Q. And was it generally the case

1 that the written report summarized the --
2 your findings with regard to their CSA
3 compliance?

4 A. Based upon what they were
5 asking for, yes.

6 Q. And described the investigation
7 that you had done?

8 A. We had some details on the type
9 of inspection.

10 Q. And would also provide -- if
11 your investigation identified deficiencies
12 with regard to CSA compliance, would the
13 report identify those deficiencies?

14 MR. DAVISON: Objection.

15 THE WITNESS: Yes. If we found
16 deficiencies or enhancements, we
17 recommended the recommendations.

18 QUESTIONS BY MR. LOESER:

19 Q. And as you just said, you'd
20 then, in your report, generally provide
21 recommendations to how -- for how to cure
22 those deficiencies; is that right?

23 A. If it was actually a
24 deficiency -- well, if we're talking a
25 regulatory issue or -- regulatory issue or

1 just a business consideration, we would
2 recommend enhancements.

3 Q. You would recommend
4 enhancements when you identified deficiencies
5 with regard to compliance with CSA
6 regulations and requirements?

7 A. Yes.

8 Q. And when you were hired to
9 provide guidance to your DEA registrant
10 clients with regard to their CSA compliance,
11 did you view that as important work?

12 A. Yes.

13 Q. And you always took that work
14 seriously?

15 A. Yes.

16 Q. And has it been your practice
17 to carefully monitor DEA guidance and
18 pronouncements regarding the Controlled
19 Substances Act and implementing regulations?

20 A. Yes.

21 Q. And have you done this so you
22 can advise your clients appropriately about
23 what they need to do to comply with the law?

24 A. Yes.

25 Q. And when you conduct an audit

1 or an evaluation of a DEA registrant client,
2 are you thorough?

3 A. Yes.

4 Q. And are you careful?

5 A. Yes.

6 Q. And do you provide truthful and
7 accurate information to your clients?

8 A. Yes.

9 Q. And we discussed this some
10 before, but do you accurately describe the
11 legal requirements of the CSA and the
12 implementing regulations of the CSA?

13 A. We didn't do any legal -- we
14 didn't get into the legal area. We left that
15 up to the attorneys.

16 Q. And so did you accurately
17 describe the regulatory requirements of the
18 CSA and the implementing regulations?

19 A. Yes.

20 Q. And did you accurately portray
21 your understanding of how the DEA interpreted
22 the CSA and its implementing regulations?

23 A. It was more of a -- our
24 understanding of the regulations that we
25 would apply or if DEA had any guidance. DEA

1 may look at something one way, you know, so
2 it really -- it was regulatory expertise,
3 looking at either guidance or the
4 regulations.

5 Q. And when you were describing
6 for your clients DEA guidance, did you
7 describe DEA guidance, in your view,
8 accurately?

9 A. We -- keep in mind, we're not
10 speaking for the Agency. But as far as we
11 knew it was accurately -- yes, we would try
12 to be as accurate as possible.

13 Or we may recommend they
14 contact DEA on a number of occasions.

15 Q. And did you give your clients
16 guidance and advice that was consistent with
17 your understanding of your clients'
18 regulatory obligations under the CSA?

19 A. Yes.

20 Q. You didn't mislead your DEA
21 registrant clients, did you?

22 A. Never.

23 Q. Or distort the law?

24 A. Not at all.

25 Q. Or spin the law in any way?

1 A. Not at all.

2 If somebody wanted us do that,
3 we'd walk away from them.

4 Q. And you didn't make up legal
5 requirements that didn't, in your view,
6 actually exist?

7 A. We never talked about any legal
8 requirements.

9 Q. And you didn't make up
10 regulatory requirements that in your view did
11 not exist?

12 A. No, we based everything on what
13 we thought the regulations were and also
14 industry standards and any guidance DEA put
15 out.

16 Q. And you advised your clients to
17 take the actions that you thought they needed
18 to take in order to fully comply with the
19 regulatory requirements?

20 MR. DAVISON: Objection.

21 THE WITNESS: From a regulatory
22 perspective, we may have recommended
23 they talk to DEA, as I said, or even
24 to their counsel.

25

1 QUESTIONS BY MR. LOESER:

2 Q. And, sir, do you stand behind
3 the audits and the evaluations that you've
4 done in the past for your clients?

5 A. Yes.

6 Q. Did you ever give presentations
7 at industry events and meetings?

8 A. Yes.

9 Q. And would you say that these
10 presentations were in the regular course of
11 your business?

12 A. Yes.

13 Q. And when you gave these
14 presentations, did you truthfully and
15 accurately describe your understanding of the
16 CSA and its implementing regulations?

17 A. Yes.

18 Q. And during those presentations
19 when you discussed DEA guidance, did you
20 truthfully and accurately state your
21 understanding of the DEA guidance?

22 A. DEA guidance, DEA regulations,
23 industry standards, it really depends on what
24 they -- what they were asking -- what we were
25 asked to present on. So it may be DEA

1 guidance or what's going on in the industry
2 today, what's the state requirement. It
3 really depends on the situation.

4 Q. And with regard to all of those
5 things, you provided what you viewed as
6 truthful and accurate information?

7 A. From a regulatory perspective,
8 yes.

9 Q. And you stand by this work as
10 well?

11 A. Yes.

12 Q. Mr. Buzzeo, can you define for
13 me what an algorithm is?

14 MR. DAVISON: Objection.

15 Sorry, go ahead.

16 THE WITNESS: Keep in mind, I'm
17 not an expert when it comes to
18 statistical models, algorithms, stuff
19 like that.

20 My understanding is that's
21 something to do with purchases for a
22 given period of time, maybe a running
23 period of time, for 6 months or 8
24 months or 12 months, and then there'd
25 be a standard deviation.

1 QUESTIONS BY MR. LOESER:

2 Q. And just in terms of the
3 meaning of the term "algorithm," do you have
4 an understanding of what it is?

5 A. My understanding is what I just
6 described.

7 Q. Is it a -- is it math? Is it a
8 calculation?

9 A. It can be math, calculation.

10 Q. Okay. And is it something like
11 2 times X is an algorithm?

12 A. Yeah, 2 times X, 3 times X.

13 Q. And, sir, what is a
14 threshold-based system?

15 A. It's when -- like you take
16 an -- let's take an average of all your sales
17 and your certain customer base and you divide
18 it out. That could be one of the ways to
19 have a threshold.

20 Q. And, sir, is there a problem
21 with relying on a threshold-based system in a
22 registrant's SOM program?

23 MR. DAVISON: Objection.

24 THE WITNESS: It really depends
25 on the registrant, depends on the

1 class of trade they have. It really
2 depends on a lot of things and what
3 you really recommend for an SOM
4 program.

5 QUESTIONS BY MR. LOESER:

6 Q. And are you familiar with any
7 guidance that has been provided by the DEA as
8 to whether a threshold-based system is
9 appropriate under the CSA?

10 A. I think there was something in
11 one of the letters. I'd have to refresh my
12 memory, but I think there's something in
13 there that talks about systems previously
14 approved but not currently -- you know, the
15 DEA made no recommendations on.

16 Q. Do you have any recollection of
17 whether the DEA indicated that a
18 threshold-based system was not adequate?

19 MR. DAVISON: Objection.

20 THE WITNESS: I don't recall.

21 QUESTIONS BY MR. LOESER:

22 Q. Now, sir, do you agree that an
23 adequate suspicious order monitoring program
24 measures the size of an order? Is that one
25 of the things that it measures?

1 A. Size, frequency, pattern.

2 Q. Okay. So you mentioned three
3 things.

4 Are those -- all of those
5 things are required to be measured in an
6 adequate suspicious order monitoring program?

7 A. As the regulation reads, they
8 give those as three standards.

9 Q. And can an algorithm be used to
10 measure these factors?

11 A. Could.

12 Q. Can you give me an example of
13 how that would work?

14 A. Let's say it's a pending --
15 it's a order that you -- based upon a number,
16 let's say, 8,000, 10,000, whatever that
17 number is, and anything exceeds that would
18 pend to make a determination if it's
19 suspicious or not.

20 Q. And when you say "exceeds
21 that," can you give me an example of what
22 metric would be used to indicate whether
23 something exceeds?

24 A. If the order exceeds 8,000 in a
25 given period of time, so let's say 30 days,

1 that could be a metric, and that would pend
2 the order.

3 Q. And is it a CSA compliance
4 problem if a SOM program doesn't take into
5 account all three of these factors: size,
6 frequency and pattern?

7 MR. DAVISON: Objection.

8 THE WITNESS: If you have a
9 program in place, those things could
10 be done by different elements of your
11 program.

12 So just one system, one
13 algorithm, doesn't have to do all
14 three of them. But you have to do all
15 three of them to have a successful
16 program.

17 QUESTIONS BY MR. LOESER:

18 Q. And if you don't have all three
19 of those things, does your program then not
20 comply with the CSA?

21 A. It's possible --

22 MR. DAVISON: Objection.

23 THE WITNESS: -- depending on
24 the details.

25

1 QUESTIONS BY MR. LOESER:

2 Q. Is it possible not to have one
3 or more of those items in your program and
4 have the program still comply with the CSA?

5 MR. DAVISON: Objection.

6 THE WITNESS: In some manner,
7 you should be looking at the entire
8 regulation and what is required.

9 QUESTIONS BY MR. LOESER:

10 Q. So the regulations require that
11 you measure all three of those factors; is
12 that right?

13 A. Yes.

14 MR. DAVISON: Objection.

15 QUESTIONS BY MR. LOESER:

16 Q. If an order is flagged as
17 potentially suspicious by a registrant SOM
18 program or SOM program, is there a
19 requirement to investigate the flagged
20 orders?

21 MR. DAVISON: Objection.

22 THE WITNESS: If the system, in
23 my terminology, pends an order, you
24 have to make a determination if it's
25 suspicious or not suspicious.

1 QUESTIONS BY MR. LOESER:

2 Q. And is that determination what
3 you refer to as due diligence?

4 A. Due diligence.

5 Q. And what is required -- let's
6 start with a manufacturer.

7 What is a manufacturer required
8 to do with regard to due diligence on what
9 you're calling a pending order?

10 MR. DAVISON: Objection.

11 THE WITNESS: There's nothing
12 in the regulation that requires
13 anything. The only thing the
14 regulation requires is you report
15 suspicious orders.

16 QUESTIONS BY MR. LOESER:

17 Q. And in all your years and
18 experience advising opioid manufacturers,
19 what is your understanding of what the due
20 diligence must include?

21 MR. DAVISON: Objection.

22 THE WITNESS: Due diligence?

23 Well, again, depending on the
24 customer base, the number of customers
25 you have, the type of customers you

1 have, due diligence can include
2 telephone communication, on-site
3 visits, questionnaires, sales --
4 customer sales reps looking at it,
5 security looking at it.

6 It really depends on the --
7 these other issues of the client --
8 you know, the customer or their
9 customer base. The registrant or the
10 customer base.

11 QUESTIONS BY MR. LOESER:

12 Q. And based on all the reviews
13 that you've done, what are some examples of
14 when due diligence has not been performed
15 adequately by a manufacturer?

16 MR. DAVISON: Objection.

17 THE WITNESS: I don't think
18 there was -- repeat the question
19 again. I want to make sure I
20 understand the question.

21 QUESTIONS BY MR. LOESER:

22 Q. In the course of auditing DEA
23 registrants, including manufacturers, did you
24 ever come across due diligence that you
25 believed was inadequate?

1 MR. DAVISON: Objection.

2 THE WITNESS: Due diligence

3 that needed some enhancements, I've

4 come across.

5 QUESTIONS BY MR. LOESER:

6 Q. Can you give some examples of
7 due diligence that needed some enhancements?

8 A. Well, again, depending -- I
9 don't recall them all, but in generalities,
10 if you have a registrant, again, depending on
11 the customer base, you may want to do on-site
12 visits. Or --

13 Q. When would you want to do
14 on-site visits?

15 A. Depending on the customer base
16 you have.

17 Q. Okay. Well, what would be an
18 example of when an on-site visit would be
19 appropriate?

20 A. If there's a spike in a given
21 area, you may want to go look at the
22 registrants that are in that area.

23 Q. And what would you look for
24 when you visited the registrant in that area?

25 A. Well, it depends on who I am as

1 a registrant and what my customer base is.

2 Q. Let's say you're visiting a
3 pain clinic. What would you look for?

4 A. Oh, the type of -- how many
5 people are coming in and out, license plates.

6 Q. Why license plates?

7 A. Well, if they come in from out
8 of state to a particular pain clinic.

9 Q. And why is that important?

10 A. Well, if you have pain, why
11 would you be driving to another state?
12 That's the question.

13 Now, there could be a
14 legitimate reason for it. Not everybody
15 drives into a pain clinic from another state.
16 It could be, in fact, you know, an illicit
17 activity. But it's things you look at.

18 Do they pay cash.

19 Q. And why does that matter?

20 A. Most people have insurance of
21 some type.

22 Or, you know, they hand you a
23 baggy with the pills in it.

24 You talk to the professional on
25 staff, and are they professional, aren't they

1 a professional.

2 Do they provide alternative
3 services? Not everybody needs pain
4 medication. Do they have alternative
5 services? Do they have physical therapy?

6 I was in one place one time,
7 they had good credentials, they had all this
8 physical therapy stuff, and when they showed
9 it to you, it was all stacked with boxes.
10 That tells you right away that something is
11 not right here.

12 The patients were walking out
13 with bags of pills. That's something not
14 right here.

15 They were -- they had to pay
16 cash at the window before they went into the
17 back. That's not right.

18 So those are some of the things
19 you look for.

20 Q. And would you say those things
21 are red flags for diversion?

22 MR. DAVISON: Objection.

23 THE WITNESS: Red flags for an
24 activity that needs to be looked at
25 further. And possibly for pain

1 clinics I looked at, it did reflect
2 diversion. But not all of them. Some
3 of them are completely legitimate.

4 QUESTIONS BY MR. LOESER:

5 Q. Is it enough for due diligence
6 just to determine if a customer has a DEA
7 registration?

8 MR. DAVISON: Objection.

9 THE WITNESS: Well, as you
10 know, the DEA registration is required
11 by -- you got to look at it --
12 required by regulation. You have to
13 verify.

14 DEA and the regulations and the
15 Act has put forth, I think, 14 or 15
16 things you have to look at. And the
17 DEA, for non-practitioners, we do it
18 every year, and the same things are
19 looked at by the Agency.

20 So it should be adequate, but
21 you do have to look further because
22 something could happen during a, you
23 know, period of time.

24 QUESTIONS BY MR. LOESER:

25 Q. So just checking to see if the

1 recipient of controlled substances has a DEA
2 registration is not a complete and adequate
3 due diligence?

4 MR. DAVISON: Objection.

5 THE WITNESS: Again, it depends
6 on the type of registrant --

7 QUESTIONS BY MR. LOESER:

8 Q. Well, when would it ever be the
9 case that determining that someone has a DEA
10 registration is adequate due diligence?

11 A. You have to check and see
12 whether everybody has a registration.

13 Q. Okay. But when would that be
14 all that is necessary for due diligence?

15 MR. DAVISON: Objection.

16 THE WITNESS: I doubt people
17 would just do that. Usually on a new
18 customer or something, they want to
19 see the operation.

20 QUESTIONS BY MR. LOESER:

21 Q. Okay. So it never would be
22 adequate due diligence just to check to see
23 if there was a DEA registration?

24 MR. DAVISON: Objection.

25 THE WITNESS: It really depends

1 on the customer base you're looking
2 at.

3 QUESTIONS BY MR. LOESER:

4 Q. So for what customer base would
5 it be adequate due diligence just to check to
6 see if there was a DEA registration?

7 A. It depends -- I'm just giving
8 you -- like you're asking hypothetical
9 questions. I'm trying to give you answers
10 that -- some of the things you'd look at. It
11 would be, is it adequate. How long have they
12 been a customer of mine. Do I have to do it
13 every -- do I do it every single time. Do I
14 only do it when I get an order. It's things
15 like that.

16 Q. Right. And I'm asking you a
17 simpler question.

18 Is it ever adequate due
19 diligence just to check to see if there's a
20 DEA registration?

21 MR. DAVISON: Objection.

22 THE WITNESS: I've never in my
23 career seen that. They usually look
24 further.

25

1 QUESTIONS BY MR. LOESER:

2 Q. So you would agree that it
3 would not be adequate due diligence just to
4 check for a DEA registration?

5 MR. DAVISON: Objection.

6 THE WITNESS: Well, when you're
7 checking registration, are you also
8 checking the security. Are you going
9 on site to do it. It's things like
10 that.

11 QUESTIONS BY MR. LOESER:

12 Q. If the only due diligence
13 that's conducted of a pended order is
14 checking to see if there's a DEA
15 registration --

16 A. I've never seen that in my
17 client base.

18 Q. And would that ever be
19 adequate?

20 MR. DAVISON: Objection.

21 THE WITNESS: You should be
22 checking further than just a
23 registration.

24 QUESTIONS BY MR. LOESER:

25 Q. So it would not be adequate?

1 MR. DAVISON: Objection.

2 THE WITNESS: Probably not.

3 QUESTIONS BY MR. LOESER:

4 Q. Is it a problem for a
5 manufacturer to rely too heavily on customer
6 service staff or salespeople when conducting
7 due diligence on pending orders?

8 A. Not at all. Depending on what
9 program you have, what type of registrant you
10 are, you want to bring as many people as
11 possible into that.

12 As I mentioned earlier, you're
13 looking at your customer service reps, you're
14 looking at product managers. You may bring
15 security in on it, bring compliance in on it.
16 They're responsible for it in the company,
17 most companies. You bring legal into it.
18 You're bringing a lot of people to get by in,
19 into that process.

20 Q. Would it be a problem -- would
21 it be adequate due diligence just to rely on
22 customer service and salespeople to conduct
23 due diligence on pending orders?

24 A. Well, depending on your client
25 base, it would be part of your program. I

1 would say it has to be part of your program.

2 Q. Right. But --

3 A. And I don't know of many
4 programs that just has the customer sales rep
5 look it. They usually expand it to have
6 their compliance people involved in the
7 process because it's -- that's where the
8 responsibility lies. They make the final
9 decisions, as does legal, involved in the
10 process.

11 Q. Would you agree that it would
12 not be appropriate to rely solely on your
13 salespeople or customer service staff to
14 conduct due diligence on pending orders?

15 MR. DAVISON: Objection.

16 THE WITNESS: Unless I have
17 more details on it, I -- it's hard for
18 me to answer that question.

19 QUESTIONS BY MR. LOESER:

20 Q. So can you think of
21 circumstances where it would be appropriate
22 to rely solely on salespeople and customer
23 service staff to conduct due diligence on
24 pending orders?

25 A. I'd have to have the details on

1 it.

2 MR. DAVISON: Objection.

3 THE WITNESS: I'd have to the
4 details on the type of registrant.

5 QUESTIONS BY MR. LOESER:

6 Q. So you can't answer whether it
7 would be inappropriate to rely solely on
8 customer service and salespeople to conduct
9 due diligence?

10 MR. DAVISON: Objection.

11 THE WITNESS: It depends on the
12 customer base. It depends if I'm
13 dealing with 5 clients or 10,000
14 clients.

15 QUESTIONS BY MR. LOESER:

16 Q. Have you ever advised --

17 A. What's the role the customer
18 sales rep does.

19 Q. Sir, have you ever advised your
20 DEA registrant clients that it would not be
21 appropriate to rely too heavily on their
22 customer service or sales personnel?

23 A. The regulation really doesn't
24 address that issue. The regulation says,
25 this is what you have to do. And based upon

1 the regulations, you could put any system you
2 want into place as long as you're meeting
3 that regulatory requirement of reporting
4 suspicious orders.

5 So to say somebody can't be
6 involved in it or this person shouldn't be
7 involved in it, it's a difficult question to
8 answer.

9 Q. So I'm going to use the term
10 "too heavily." I'm going to ask you, so that
11 we're clear what we're talking about: Do you
12 believe it would be a problem for a DEA
13 registrant, a manufacturer, to rely too
14 heavily on sales staff and customer service
15 staff to conduct due diligence on pended
16 orders?

17 MR. DAVISON: Objection.

18 THE WITNESS: I think it's an
19 element in your program that should be
20 relied upon.

21 MR. LOESER: Can you read the
22 question back, please?

23 (Court Reporter read back
24 question.)

25 THE WITNESS: Again, as I said,

1 it really depends on the registrant
2 and their customer base.

3 And I don't know what "too
4 heavily" means. If they're
5 providing -- you want as many
6 people -- as many employees of that
7 company or operations in that company
8 involved in the process, as long as
9 the final decision is made by
10 compliance and legal.

11 QUESTIONS BY MR. LOESER:

12 Q. So in the context of the
13 question I just asked you, you don't know
14 what too heavily means?

15 A. Oh, I know what too heavily
16 means, but, again, too heavily on one company
17 may be -- you know, two individuals or maybe
18 all they do -- it really depends on the
19 registrant you're dealing with, the customer
20 base they have.

21 Q. So you would never advise any
22 of your DEA registrant clients not to rely
23 too heavily on customer service or sales
24 personnel?

25 MR. DAVISON: Objection.

1 THE WITNESS: I would recommend
2 that a large majority of your
3 operations in that company be involved
4 in the process, as long as compliance
5 and legal have the final say on what's
6 being reported as suspicious.

7 MR. LOESER: Can you read the
8 question back, please?

9 (Court Reporter read back
10 question.)

11 MR. DAVISON: Objection. Asked
12 and answered.

13 QUESTIONS BY MR. LOESER:

14 Q. Can you answer that question,
15 please?

16 A. Excuse me?

17 Q. Can you answer that question?

18 A. I did answer the question. So
19 let me -- look, what I'm saying is is that
20 when you build a program in a company, a
21 suspicious order monitoring program, not just
22 an algorithm but a program, you want as many
23 people in that company involved in the
24 process: security -- or compliance, let's
25 start with compliance, number one --

1 security, legal, sales and marketing, to be
2 part of the program, because you want the
3 entire company to have buy-in.

4 So customer sales reps would be
5 involved in the program, product managers,
6 depending on the type of company, would be
7 involved in the program, security, all these
8 other elements, as long as compliance and
9 legal make the final decision.

10 Q. So let me ask it this way.

11 Do you agree or disagree with
12 the following statement: Customer service
13 and sales personnel should not be relied on
14 too heavily when conducting due diligence on
15 pending orders?

16 Do you agree with that
17 statement or disagree with that statement?

18 MR. DAVISON: Objection.

19 THE WITNESS: I believe that
20 they should be part of the process.

21 QUESTIONS BY MR. LOESER:

22 Q. And is it a problem to rely too
23 heavily on them?

24 MR. DAVISON: Objection.

25 THE WITNESS: Well, are you

1 relying too heavily on security? Are
2 you relying too heavily on legal?
3 It's not a yes or no question.

4 QUESTIONS BY MR. LOESER:

5 Q. Okay. So you can't answer the
6 question whether it's a problem to rely too
7 heavily on sales and customer service
8 personnel?

9 That's all I'm asking you, is
10 if --

11 A. I know. But I'm answering the
12 question saying it really depends on the type
13 of program you have, who you rely on and what
14 role they play in it.

15 Q. So the answer to my question
16 is, no, you can't answer that question?

17 MR. DAVISON: Objection.

18 THE WITNESS: I didn't say no;
19 I didn't say yes. I'm just saying the
20 type -- the registrant has to
21 determine who their customer base is,
22 what sales they make, what type of
23 drugs they have, and who should be
24 involved in the company -- in the
25 program.

1 And as many elements or silos
2 that you have in the company should be
3 involved in the process, not making
4 final decisions but involved in the
5 process.

6 So I can't really say yes or no
7 on that question.

8 QUESTIONS BY MR. LOESER:

9 Q. And that's not something you
10 would ever advise your clients then?

11 A. Excuse me?

12 Q. That's not something you would
13 ever advise your clients of?

14 A. Oh, we would advise clients,
15 depending on the other elements that I said.

16 Q. Would you advise your clients
17 not to rely too heavily on sales personnel or
18 customer service personnel?

19 MR. DAVISON: Objection.

20 THE WITNESS: I would advise
21 clients and the company would advise
22 clients that we want to include as
23 many people. So if we went into a
24 company and, say, security was
25 involved, we would say, you should

1 involve security.

2 HR is not involved. Well,
3 maybe you should involve HR but on
4 a -- more on the perimeter.

5 Sales and marketing should be
6 involved so they have a good
7 understanding of what a suspicious
8 order is, what people should be
9 looking for.

10 You don't want to make cops out
11 of your sales reps or your
12 salespeople, but you want them
13 involved to have an understanding of
14 the program.

15 QUESTIONS BY MR. LOESER:

16 Q. Sir, have you ever advised any
17 DEA registrant client not to rely too heavily
18 on customer service or sales personnel to
19 investigate pended orders?

20 MR. DAVISON: Objection.

21 QUESTIONS BY MR. LOESER:

22 Q. Yes or no?

23 A. At this point, in all the years
24 I've had in this, my best answer I can give
25 you on that is, depending -- as I've been

1 saying right along, depending on your
2 customer base, the type of registrant you're
3 dealing with, the type of drugs, you want as
4 many people involved in the process and all
5 to play a role in that process, as long as
6 your decision is made by compliance operation
7 and legal.

8 Q. Have you ever advised any DEA
9 registrant client not to rely too heavily on
10 customer service or sales personnel to
11 conduct due diligence on pended orders?

12 MR. DAVISON: Objection. Asked
13 and answered.

14 QUESTIONS BY MR. LOESER:

15 Q. You either have or haven't or
16 you don't recall.

17 A. What I'm trying to say to you
18 is --

19 Q. I understand what you're trying
20 to say, but I'm trying to get you to answer
21 whether you have or have not provided that
22 guidance, or if you don't recall, if that's
23 the case.

24 MR. DAVISON: Objection.

25 THE WITNESS: I don't recall,

1 because we'd usually have a discussion
2 about who should be involved in the
3 program and what role they should
4 play.

5 So a customer sales rep would
6 have a better handle on what the
7 ordering pattern is, what they usually
8 order, what type of company they are,
9 and that should be brought into the
10 process of making the final decision.

11 QUESTIONS BY MR. LOESER:

12 Q. So your answer --

13 A. I'm not ignoring your question.
14 I'm just trying to give you a straight answer
15 of how the process should work from a
16 regulatory perspective.

17 Q. So your answer is you don't
18 recall?

19 MR. DAVISON: Objection.

20 QUESTIONS BY MR. LOESER:

21 Q. Is that what you're saying?

22 A. No, what I'm saying is --

23 Q. I don't need to hear the whole
24 explanation again. I'm asking you a
25 straightforward question.

1 Have you advised your clients
2 not to rely too heavily on customer service
3 and sales personnel, or have you not advised
4 your clients of that?

5 MR. DAVISON: Objection. Asked
6 and answered I think seven or eight
7 times now.

8 THE WITNESS: What I've said --
9 QUESTIONS BY MR. LOESER:

10 Q. Sir, I don't need to hear the
11 whole explanation again. What I'd like --

12 A. Then I can't answer your
13 question because there's times when we advise
14 them --

15 Q. So the answer is, yes, you have
16 sometimes --

17 A. No. There's time -- you told
18 me not to step on your questions.

19 There's time when you want to
20 advise them that they should be included and
21 the role they should play in the process,
22 just like you advise that if security is not
23 involved, they should be involved in the
24 process and what role they should play. And
25 so in order to build a program, that's what

1 you're doing.

2 For me to stand here and say,
3 no, they shouldn't be involved, they're
4 involved too much, I'd have to have all the
5 details in front of me, and I'd have to be
6 aware of who the client -- the customer is,
7 the registrant is.

8 Q. So I have not asked you whether
9 they should be involved. I've asked you
10 whether you've before advised your clients
11 not to rely too heavily on sales personnel
12 and customer service reps.

13 A. And I'm telling you I can't
14 answer that question. It really depends
15 on --

16 Q. Have you ever advised clients
17 on that?

18 MR. DAVISON: Objection.

19 THE WITNESS: I don't recall.

20 QUESTIONS BY MR. LOESER:

21 Q. Mr. Buzzeo, what specifically
22 should a manufacturer know about its customer
23 in order to adequately know its customer for
24 purposes of CSA compliance?

25 MR. DAVISON: Objection.

1 THE WITNESS: Are they
2 registered. Do whatever checks they
3 do on it. They've been on site
4 probably before they establish a new
5 customer. If you have customer sales
6 reps and product managers, they've
7 been on site. Your compliance people
8 will go out and look at the operation
9 in some cases, depending on the
10 situations and how often.

11 It's things like that you're
12 looking at.

13 QUESTIONS BY MR. LOESER:

14 Q. Are there particular red flags
15 a manufacturer should look for when
16 evaluating orders by its distributor
17 customers?

18 MR. DAVISON: Objection.

19 THE WITNESS: Well, you look at
20 the same thing from -- if you're
21 looking at the regulatory issues. You
22 know, what quantities are they buying,
23 what type of drugs, patterns, things
24 like that, but keeping in mind that
25 that could vary, especially when

1 you're dealing at the wholesale level.

2 Their client base may change.

3 Maybe there's a recall on somebody
4 else's product so your product may be
5 up at that point in time.

6 So, again, there's this --
7 there's a lot of things you have to
8 look at before you make those
9 decisions.

10 QUESTIONS BY MR. LOESER:

11 Q. And is there a set of red flags
12 that you would look for every time in an
13 adequate --

14 A. The ones I gave you. We're
15 talking about the practitioner -- the
16 non-practitioner level, correct?

17 Q. Right.

18 A. Yeah.

19 Q. Sir, is it important for a
20 manufacturer or registrant to pay attention
21 to what media reports say about the state or
22 geographical area where its controlled
23 substances are being shipped by its
24 distributor customers?

25 MR. DAVISON: Objection.

1 THE WITNESS: Well, it's one
2 thing that you would look at. If you
3 got media reports like Mallinckrodt
4 did, media reports of high
5 distribution into Florida, they looked
6 at that very carefully and they put
7 some -- they took some steps, put some
8 steps in place.

9 QUESTIONS BY MR. LOESER:

10 Q. And why would you look at that?

11 A. Well, it's a source of
12 information.

13 Q. Is it a source of information
14 about diversion?

15 A. It's a source -- not
16 necessarily diversion -- until you look at it
17 to determine whether it's diversion or not,
18 it's a source of information.

19 Q. Information of what? What kind
20 of information?

21 A. Patterns, maybe, what's going
22 on in that given area.

23 Q. So circumstances that the
24 manufacturer should take into account in its
25 SOM program?

1 MR. DAVISON: Objection.

2 THE WITNESS: Well, again, as
3 you know, there's no regulatory
4 required for it, but if something --
5 if you see something going on, that
6 there's some steps that you would
7 take.

8 QUESTIONS BY MR. LOESER:

9 Q. And you would take those steps
10 so that you didn't allow diversion to occur
11 when you could otherwise stop it?

12 MR. DAVISON: Objection.

13 THE WITNESS: It's -- you
14 don't -- you don't want to see a
15 product -- if you become aware of --
16 to the news media, let's say, that
17 there's a problem in a given area,
18 you're going to react to it.

19 And like Mallinckrodt did, they
20 reacted to it, they took certain
21 steps. And there's a number of
22 clients -- not clients, but
23 registrants, that will do that.

24 QUESTIONS BY MR. LOESER:

25 Q. And so what actions should a

1 company take when it identifies that a
2 particular geographic area where it's
3 products are being shipped has -- there are
4 reports that there's widespread diversion in
5 that area?

6 MR. DAVISON: Objection.

7 THE WITNESS: Maybe audits,
8 audits of -- if you have a distributor
9 in that given area or -- you do an
10 audit of that distributor or some type
11 of review of that distributor.

12 QUESTIONS BY MR. LOESER:

13 Q. And would you say the same is
14 true for distributors?

15 A. Distributors have a completely
16 different customer --

17 Q. If there's reports of a
18 particular problem of diversion in an area,
19 should the distributor also pay attention to
20 those reports and take that information into
21 account in its SOM program?

22 MR. DAVISON: Objection.

23 THE WITNESS: Again, depending
24 on the customer base they have -- and
25 I can just answer this just in

1 generalities. The customer base they
2 have, type of drugs, area, there would
3 be probably some type of due
4 diligence.

5 QUESTIONS BY MR. LOESER:

6 Q. And the distributor, just like
7 the manufacturer, would want to do that due
8 diligence so that it could take it into
9 account in its SOM program?

10 MR. DAVISON: Objection.

11 THE WITNESS: The due diligence
12 could be whatever. It could be news
13 media, it could be telephone calls, it
14 could be whatever, but to look at the
15 issue.

16 QUESTIONS BY MR. LOESER:

17 Q. You're saying distributors
18 should look at that information as well?

19 MR. DAVISON: Objection.

20 THE WITNESS: I didn't say
21 that. I said depending on the issue,
22 depending on the customer base,
23 depending on what you're -- what
24 you're aware of.

25

1 QUESTIONS BY MR. LOESER:

2 Q. But you can't think of any
3 reason why a distributor would not want to
4 pay attention to media reports of diversion
5 in an area of where it's shipping its
6 products?

7 MR. DAVISON: Objection.

8 THE WITNESS: I think everybody
9 should have a suspicious order
10 monitoring program in place where
11 they're looking at orders and make a
12 determination whether somebody is
13 suspicious or not suspicious.

14 QUESTIONS BY MR. LOESER:

15 Q. Okay. And so the distributor,
16 like the manufacturer, should pay attention
17 to media reports of diversion in particular
18 geographic areas, right?

19 MR. DAVISON: Objection.

20 THE WITNESS: What I'm saying
21 is, is that it's something -- if they
22 become aware of something, they would
23 react to it.

24 QUESTIONS BY MR. LOESER:

25 Q. They should react to. Is that

1 what you're saying?

2 MR. DAVISON: Objection.

3 THE WITNESS: It would

4 determine what was causing it.

5 Don't forget, there's a lot of

6 anecdotal information out there, and

7 you want to make sure you don't get

8 involved in that. And there's even

9 examples of that, where there was all

10 this so-called diversion. Went and

11 out did reviews on it, there was

12 nothing. There was one case, and they

13 built it into a hundred.

14 QUESTIONS BY MR. LOESER:

15 Q. Are manufacturers required to

16 monitor what their customers' customers do

17 with controlled substances made by the

18 manufacturer?

19 A. There's nothing in the

20 regulations that addresses that.

21 Q. And so are you saying that they

22 are not required to monitor that?

23 A. There's no requirement in the

24 regulations.

25 Q. So again, are you saying that

1 therefore manufacturers --

2 A. And even DEA has said that.

3 Q. So, sir, you're saying that
4 there's no requirement for manufacturers to
5 monitor what their customers' customers are
6 doing with the manufacturers' products?

7 A. There's no regulatory
8 requirement that requires you to look at your
9 customers' customer, no matter what --
10 whether you're a manufacturer or distributor
11 or a pharmacy that's distributing.

12 Q. And so, sir, are you saying
13 that based on that, it's not necessary for
14 the manufacturer to evaluate its customers'
15 customers?

16 A. It's not -- it's -- DEA doesn't
17 even require -- didn't require you to do
18 that. There was nothing in the regulations
19 require you to do it.

20 Q. And so --

21 A. And if we go ahead and start
22 monitoring our customers, or customers'
23 customers, we'll end up with a medicine
24 cabinet.

25 Q. So what you're saying is that

1 you do not believe manufacturers have an
2 obligation to monitor their customers'
3 customers; is that what you're saying?

4 A. Yes, they have no obligation.

5 Q. As part of a manufacturer's SOM
6 program, should the manufacturer evaluate
7 the -- what particular drugs its customers
8 are ordering?

9 A. Particular drugs?

10 Q. Yeah.

11 A. Well, they should monitor all
12 controlled substances.

13 Q. Okay. And should manufacturers
14 look at the ratio of controlled substances to
15 noncontrolled substances purchased by its
16 distributor customers?

17 MR. DAVISON: Objection.

18 THE WITNESS: That's more for
19 pharmacy activity.

20 QUESTIONS BY MR. LOESER:

21 Q. That's not something that
22 manufacturers should do when evaluating
23 distributor orders?

24 A. To me, that's a red flag for
25 the practitioner level. Your customer is

1 paying cash, your customer has insurance.
2 Are you only ordering controlled drugs and
3 not noncontrolled drugs. Do you have fun
4 items. Do you have toothpaste, aspirin,
5 stuff like that. That's a red flag for the
6 pharmacist.

7 Q. Should manufacturers look to
8 see if their distributor customers are
9 ordering just certain controlled substances,
10 for example, those that are known to be
11 abused and diverted?

12 A. What you have to look at is the
13 circumstances behind it. Because let's say I
14 get a better price from somebody else. I'll
15 buy one drug from that other manufacturer,
16 buy another drug from another manufacturer.
17 It's not just a yes or no
18 question.

19 Q. So is that something that if a
20 manufacturer is evaluating its wholesale
21 distributor customers' orders -- they do have
22 to evaluate their wholesale distributor
23 customers' orders, right?

24 A. They have a suspicious order
25 monitoring program in place.

1 Q. Okay. And should that
2 suspicious order monitoring system evaluate
3 whether the wholesale distributor customer is
4 buying predominantly controlled substances
5 that are known to be abused and diverted?

6 MR. DAVISON: Objection.

7 THE WITNESS: I think -- I
8 think in that situation your customer
9 sales representative may say to them,
10 hey, how come you're not buying X and
11 X from me or, you know, this
12 controlled drug instead of that
13 controlled drug.

14 And somebody may say, well, I
15 only need this from you.

16 And next time the product
17 manager goes on site, they look at
18 it -- again, it depends on the
19 customer.

20 Now, if you have a customer --
21 you know, it really depends what
22 they're buying from you. But, again,
23 it depends on the circumstances behind
24 it.

25 So if you go out on site and

1 review that, it may be nothing.

2 QUESTIONS BY MR. LOESER:

3 Q. I'll try again.

4 So when a manufacturer is
5 operating its SOM program and evaluating the
6 orders from its wholesaler distributor
7 customers, should one of the things the
8 manufacturer always evaluate is whether the
9 wholesale distributor customer is ordering
10 predominantly controlled substances that are
11 known to be abused and diverted?

12 For example --

13 MR. DAVISON: Objection.

14 QUESTIONS BY MR. LOESER:

15 Q. -- if the wholesale distributor
16 is just ordering oxycodone.

17 MR. DAVISON: Objection.

18 THE WITNESS: If the
19 manufacturer has a broad number of
20 products, let's -- or they just limit
21 it to controlled drugs, well, then you
22 would expect the wholesaler is only
23 going to buy a controlled substance
24 from you.

25 If you have a broad base, where

1 you have control and noncontrol, then
2 you may expect a wholesaler to buy
3 both from you or maybe just buy one
4 from you.

5 QUESTIONS BY MR. LOESER:

6 Q. So you agree that it would be a
7 red flag that the manufacturer should take
8 into account in its SOM program if one of its
9 customers only purchases controlled
10 substances, and within that only purchases
11 those that are most likely to be abused and
12 diverted?

13 MR. DAVISON: Objection.

14 THE WITNESS: If the only drugs
15 you're supplying is controlled
16 substances, that's not a yes or no
17 question.

18 If you're providing both
19 controlled and noncontrolled, it's
20 something you may want to look at.
21 Why are they only buying controlled
22 from you and not noncontrolled. It
23 could be a pricing issue.

24 It's something you would look
25 at.

1 QUESTIONS BY MR. LOESER:

2 Q. Are you aware of whether
3 particular prescription opioids are more
4 abused and diverted than others?

5 A. Well, today my understanding
6 is -- and I've been out of it a few years
7 now -- is some of the oxy, some of the
8 fentanyl products, hydrocodone products. And
9 then you got the lower Schedule IIIs and IVs
10 and non-narcotic that are being abused. It
11 runs the gamut.

12 But we shouldn't forget out
13 there that also we have large quantities of
14 heroin and illicit fentanyl.

15 Q. And so if a wholesale
16 distributor customer is ordering
17 predominantly oxy and that's one of those
18 that is most abused and diverted, is that
19 something that the manufacturer should take
20 into account in its SOM evaluation of that
21 wholesale distributor?

22 MR. DAVISON: Objection.

23 THE WITNESS: Those type
24 questions, without the details and
25 hypothetical questions, are extremely

1 hard to answer.

2 QUESTIONS BY MR. LOESER:

3 Q. Are there particular types of
4 businesses which -- to which wholesale
5 distributor clients ship their controlled
6 substances that you believe a manufacture
7 should be particularly concerned about?

8 A. Well, I'd like to --

9 MR. DAVISON: Objection.

10 THE WITNESS: I was retained to
11 look at a manufacturer's program, not
12 to look at the wholesaler's business
13 and what they're distributing.

14 Those, again, we get back to
15 hypothetical questions. They're too
16 general. You'd have to give me an
17 awful lot of details before I could
18 respond to that question.

19 QUESTIONS BY MR. LOESER:

20 Q. So in all of your years of
21 auditing, did you develop any understanding
22 of whether pain clinics were a problematic
23 type of business that should be taken into
24 account and evaluated in a SOM program?

25 MR. DAVISON: Objection.

1 THE WITNESS: The pain clinics
2 I looked at were problematic.

3 QUESTIONS BY MR. LOESER:

4 Q. So do you believe that a
5 manufacturer, when evaluating orders by its
6 wholesale distributors, should consider
7 whether those distributors are shipping
8 predominantly to pain clinics?

9 A. Well, it depends. Again I'll
10 ask you: Is the pain clinic associated with
11 an institution such as a hospital? Then you
12 would -- you know, you look at it maybe a
13 little differently. Is it a private clinic?

14 It really depends on the
15 circumstances and details. All I said was,
16 the ones I looked at were problematic.

17 But you may have some out there
18 completely legitimate. You got to look at
19 them carefully before you make a decision.

20 Like one of the depositions I
21 looked at said anything over 8,000 is
22 suspicious, should be reported to the DEA.
23 That doesn't make sense to me.

24 Q. Sir, do you believe it's
25 important for a manufacturer to evaluate

1 whether multiple distributors that are
2 purchasing from the manufacturer are shipping
3 to the same downstream customer?

4 MR. DAVISON: Objection.

5 THE WITNESS: You're going to
6 have to -- give me that question
7 again.

8 And I don't want to say it, but
9 try --

10 QUESTIONS BY MR. LOESER:

11 Q. Do you believe that a
12 manufacturer should evaluate whether multiple
13 of its distributor clients are shipping the
14 manufacturer's product to the same downstream
15 customer?

16 MR. DAVISON: Objection.

17 THE WITNESS: The same --

18 QUESTIONS BY MR. LOESER:

19 Q. Downstream customer?

20 A. Multiple distributors selling
21 to the same --

22 Q. Selling controlled substances
23 to the same downstream customer?

24 MR. DAVISON: Objection.

25 THE WITNESS: Same doctor, same

1 registrant --

2 QUESTIONS BY MR. LOESER:

3 Q. Right.

4 A. -- multiple distributors to the
5 same...

6 Well, yeah, you would look at
7 that from a perspective of, is it a pricing
8 issue? Is it a possible suspicious
9 situation? It may be somebody that can't get
10 the product from or is it a backorder on the
11 product or somebody's recall? So you have to
12 look at the circumstances.

13 If I'm buying from 14 different
14 manufacturers and everybody is supplying with
15 the drug, well, I need to look at that maybe
16 a little more deeper. But again, it depends
17 on the circumstances.

18 Maybe I've been buying from A
19 because -- and B but -- I was buying from A,
20 and now I'm buying from B because A is out of
21 stock, or there's a recall or something, and
22 only C has the product. So right there and
23 then, that one scenario, I've purchased from
24 all three of them over a period of time.

25 So what's the time period?

1 What's the circumstances behind it? But it's
2 something you would look at.

3 Q. It's something that if you saw
4 that the same downstream customer was
5 obtaining controlled substances from multiple
6 distributors, you would want to investigate
7 that and make sure that there wasn't
8 diversion occurring, correct?

9 MR. DAVISON: Objection.

10 THE WITNESS: Again, it depends
11 on the customer base. And like I
12 said, I was retained only to look at
13 Mallinckrodt's program. I did not get
14 into the customer bases for
15 distributors and what their functions
16 should be.

17 QUESTIONS BY MR. LOESER:

18 Q. But the circumstances that
19 we've been discussing is a potential cause
20 for concern that the registrant would want to
21 investigate, right?

22 MR. DAVISON: Objection.

23 THE WITNESS: The question I
24 thought I heard from you was, if a
25 manufacturer dealing with wholesalers

1 is -- and this wholesaler is buying
2 from multiple manufacturers.

3 QUESTIONS BY MR. LOESER:

4 Q. No. One manufacturer, multiple
5 wholesalers, shipping to the same downstream
6 customer.

7 A. Oh, I wouldn't know.

8 Q. You don't have any opinion on
9 that?

10 A. Well, it really depends on the
11 circumstances.

12 Q. So you've indicated in your
13 report that you audited a lot of registrants,
14 including pharmacies --

15 A. Uh-huh.

16 Q. -- including some pain clinics,
17 correct?

18 A. Yes.

19 Q. And if a pain clinic is
20 receiving oxy from multiple different
21 distributors, all sold by the same
22 manufacturer, is that a circumstance that you
23 think would require further investigation?

24 MR. DAVISON: Objection.

25 THE WITNESS: If you knew that

1 as factual, it was something we would
2 look at. But the only one that has
3 that --

4 QUESTIONS BY MR. LOESER:

5 Q. Why would you look at that?

6 A. Excuse me. The only one that
7 has that information is DEA through their
8 ARCOS report. Nobody else -- customer --
9 registrants don't share their customer base
10 with other registrants, usually.

11 Q. Let me try one more time.

12 If you're a manufacturer and
13 you have multiple distributors purchasing
14 your product, and all those multiple
15 distributors are sending that product to the
16 same pharmacy, the manufacturer has
17 information then showing all of those sales
18 to the pharmacy, correct?

19 A. Oh, yeah.

20 MR. DAVISON: Objection.

21 THE WITNESS: I understand the
22 question better now.

23 If the manufacturer is aware of
24 that through a chargeback program,
25 let's say, as Mallinckrodt did, they

1 would send a letter to the wholesalers
2 and to DEA, not saying it's suspicious
3 or not, but it's something that should
4 be looked at, and they would say,
5 we're not going to reimburse that
6 company for any -- reimbursement on
7 chargebacks.

8 QUESTIONS BY MR. LOESER:

9 Q. And why is it something that
10 should be looked at?

11 MR. DAVISON: Objection.

12 THE WITNESS: I mean, you gave
13 me the example. This one
14 distributor -- the multiple
15 distributors selling to one person.
16 The only one that really knows that
17 information is DEA because they -- you
18 know, DEA gets the information.

19 Now, if the manufacturer's
20 aware of that for whatever reason,
21 maybe through the chargeback program,
22 then they would look at it.

23 And as Mallinckrodt has, they
24 send a letter to distributors. We're
25 not going to honor any more

1 chargebacks, and they send copies of
2 that letter to DEA.

3 QUESTIONS BY MR. LOESER:

4 Q. And a manufacturer would do
5 that because there may be diversion occurring
6 at the downstream customer?

7 MR. DAVISON: Objection.

8 THE WITNESS: All they know is,
9 it's something that should be looked
10 at, and they're reporting to DEA so
11 DEA can look at it. It's not part of
12 their SOM program.

13 QUESTIONS BY MR. LOESER:

14 Q. Should orders flagged as
15 potentially suspicious be held until the due
16 diligence investigation is complete?

17 A. I missed the first part of your
18 question.

19 Q. Should orders flagged as
20 potentially suspicious be held until the due
21 diligence investigation is complete?

22 MR. DAVISON: Objection.

23 THE WITNESS: When you hold an
24 order that's pend till you make a
25 determination whether the order is

1 suspicious or not, then you make a
2 determination whether you're going to
3 ship it or not.

4 So if it's suspicious, you
5 report it to DEA. You make a
6 determination, do I ship or not ship.

7 There's nothing in the
8 regulation that says you can ship,
9 there's nothing that says you
10 should -- you can ship it -- can't
11 ship it.

12 QUESTIONS BY MR. LOESER:

13 Q. Sir, in your view, is it okay
14 for manufacturers to decrease the size of an
15 order to avoid triggering a suspicious order
16 flag?

17 A. No.

18 Q. What training is required for
19 the personnel who are involved in the
20 manufacturer SOM program?

21 MR. DAVISON: Objection.

22 THE WITNESS: From DEA
23 perspective?

24 QUESTIONS BY MR. LOESER:

25 Q. From the compliance

1 perspective.

2 A. There's no requirement.

3 Q. And how would you advise your
4 clients in terms of how they should train the
5 personnel involved in SOM programs?

6 A. If you handle controlled drugs,
7 you'd be aware of your responsibility and
8 requirements, depending on what function they
9 have.

10 Q. I asked you about whether a
11 threshold system was appropriate for a
12 manufacturer's SOM program, and I'll ask you
13 the same thing about distributors.

14 Is a threshold-based system
15 acceptable for a distributor's SOM program?

16 MR. DAVISON: Objection.

17 THE WITNESS: All I know is
18 what I've been hired to do is look at
19 Mallinckrodt's program, not the
20 distributor program, not how they
21 function, none of the regulatory
22 issues associated with distributors.

23 And that's a hypothetical
24 question that I really can't answer.
25 It depends -- again, I get back to the

1 same thing. It depends on the
2 customer base, what they're doing and
3 stuff like that. But --

4 QUESTIONS BY MR. LOESER:

5 Q. So is it your testimony that a
6 distributor can utilize a threshold-based
7 system for its SOM program?

8 A. I'm not -- I'm not recommending
9 what distributors do or not do. I was here
10 to evaluate Mallinckrodt's.

11 Q. And, sir, do you know if it's
12 acceptable for a distributor to use a
13 threshold-based system for its SOM program?

14 A. All I know is that not one
15 system fits all. Every -- depending on the
16 registrant and the customer base, everything
17 is different. Could be a paper-based system,
18 it could be a statistical system. It depends
19 on the customer base and the clients.

20 Again, I get back to it. I was
21 retained to look at Mallinckrodt's program
22 and make a determination on that, not the
23 distributor programs.

24 Q. So, sir, you can't answer the
25 question whether it's acceptable for a

1 distributor to use a threshold-based system?

2 MR. DAVISON: Objection.

3 THE WITNESS: It depends on the
4 customer base.

5 QUESTIONS BY MR. LOESER:

6 Q. So it may be acceptable?

7 A. I'm not saying that either. It
8 depends on the customer base, who are they
9 distributing to, number of clients they have,
10 what type of drugs.

11 Q. And so when is it acceptable
12 for a distributor to use a threshold-based
13 system?

14 MR. DAVISON: Objection.

15 THE WITNESS: Again, you're
16 asking me the same question. You need
17 to know the customer base. You need
18 to know the details about it before
19 you recommend anything to any
20 registrant.

21 It's like a pharmacy. If they
22 distribute drugs, they have to have an
23 SOM program in place.

24 Now, what's acceptable to a
25 pharmacy? I don't know unless I see

1 the type of pharmacy, I see who
2 they're distributing to, what
3 percentage of drugs they're
4 distributing, should they be
5 registered to distribute or not to
6 distribute.

7 You can't make a determination
8 or answer a question just on a
9 hypothetical. It's extremely
10 difficult.

11 QUESTIONS BY MR. LOESER:

12 Q. So in terms of the guidance you
13 provided to your clients, there was no
14 categorical rule that a distributor cannot
15 use a threshold-based system for its SOM
16 program?

17 MR. DAVISON: Objection.

18 THE WITNESS: Can -- the
19 recommendations were made were
20 entirely based -- to any registrant
21 was based upon client -- customer
22 base, types of drugs, location, things
23 like that.

24 QUESTIONS BY MR. LOESER:

25 Q. And, sir, are you aware of

1 whether the DEA ever advised distributors
2 that they could not use threshold-based
3 systems?

4 A. I'm not -- I don't recall that
5 at all.

6 Q. Does a distributor SOM need to
7 evaluate order size, frequency and pattern?

8 A. Got to --

9 Q. Does a distributor's SOM need
10 to evaluate order size, frequency and
11 pattern?

12 A. The regulation says that you
13 have to report suspicious orders, and the
14 criteria for that is such as quantity,
15 pattern, frequency, size. All those things
16 go into it.

17 Q. And I asked you before about
18 manufacturers.

19 What due diligence should a
20 distributor do for orders that are flagged as
21 suspicious?

22 MR. DAVISON: Objection.

23 THE WITNESS: It's a
24 hypothetical question again. I would
25 have to have more details on it.

1 Again, I was not hired to look
2 at or retained to look at the
3 distributors. It was the
4 manufacturer, Mallinckrodt.

5 QUESTIONS BY MR. LOESER:

6 Q. And you don't recall from all
7 the audits you've done over your 50-plus
8 years whether there are particular factors
9 that a distributor should take into account
10 when conducting due diligence of pended
11 orders?

12 A. Those factors --

13 MR. DAVISON: Objection.

14 THE WITNESS: -- are all based
15 upon the registrant and their customer
16 base that they have and what type of
17 drugs they were distributing.

18 QUESTIONS BY MR. LOESER:

19 Q. And for orders that are flagged
20 as suspicious by a distributor, should those
21 orders be held until the investigation is
22 complete?

23 MR. DAVISON: Objection.

24 THE WITNESS: Well, I go back
25 on the regulation. The regulation

1 says you're supposed to submit
2 suspicious orders. It says nothing
3 else. There's nothing else that it
4 says.

5 The registrant has to make that
6 determined -- based upon what they
7 take into consideration. And the due
8 diligence they perform is -- depends
9 on the customer base, what they're
10 selling.

11 QUESTIONS BY MR. LOESER:

12 Q. So is it your view that a
13 distributor can go ahead and ship orders that
14 it flags as suspicious without doing any due
15 diligence investigation?

16 A. I didn't say that at all.

17 MR. DAVISON: Objection.

18 QUESTIONS BY MR. LOESER:

19 Q. Is that your view?

20 A. No, I didn't say that at all.

21 What I said was, it really
22 depends on the circumstances, the customer
23 base, the types of drugs, of what a
24 registrant has to look at before they make a
25 determination to ship, don't ship.

1 Q. When can a distributor ship
2 suspicious orders without doing any due
3 diligence of the orders?

4 MR. DAVISON: Objection.

5 MS. DICIURCIO: Objection.

6 THE WITNESS: I didn't hear
7 what they said.

8 Thank you.

9 Repeat your question.

10 MR. LOESER: Sorry.

11 Read it back, please.

12 (Court Reporter read back
13 question.)

14 THE WITNESS: Again, I'll say
15 that any registrant, depending on
16 where they are in the distribution
17 chain, that has a reporting
18 requirement for suspicious orders, has
19 to make the determination if they
20 declare something as suspicious
21 whether to ship or not ship.

22 They do review and it's not
23 suspicious, they go ahead and ship the
24 product. If this is suspicious, they
25 have to make that determination.

1 The regulation only talks about
2 having a reporting requirement if --
3 and I make a determination that the
4 order is suspicious.

5 The talk about hypotheticals
6 without having all the details is
7 extremely difficult.

8 QUESTIONS BY MR. LOESER:

9 Q. Is it your understanding of the
10 law that distributors who routinely report
11 suspicious orders, yet fill those orders
12 without investigating them, are failing to
13 maintain effective controls against
14 diversion?

15 MR. DAVISON: Objection.

16 THE WITNESS: What you got to
17 look at is at one time DEA accepted,
18 up until 2006, I guess, excessive
19 order reports from the industry. It
20 was the industry standard accepted by
21 DEA, excessive order reports.

22 QUESTIONS BY MR. LOESER:

23 Q. I guess I'll try again.

24 Is it your understanding of the
25 law that distributors who routinely report

1 suspicious orders, yet fill those orders
2 without investigating them, are failing to
3 maintain effective controls against
4 diversion?

5 A. What period of time are we
6 talking about?

7 MR. DAVISON: Objection.

8 QUESTIONS BY MR. LOESER:

9 Q. Ever. Now. How about now?

10 MS. FUMERTON: This is Tara
11 Fumerton on behalf of Walmart, and I'm
12 just going to object to all of these
13 questions relating to distributors or
14 to chain pharmacies as outside the
15 scope of this deposition.

16 QUESTIONS BY MR. LOESER:

17 Q. You can answer.

18 A. As I said, I was retained by
19 Mallinckrodt to look at their program, not by
20 any distributors.

21 Your questions are
22 hypothetical. It's very difficult to answer
23 a hypothetical question without knowing all
24 the facts.

25 The only requirement in the

1 regulation is that a company has to report
2 suspicious orders. That's all it says.

3 You can -- by regulation, if
4 you want to send excessive reports in, send
5 them in, as long as you report your orders
6 when they're suspicious, that you call
7 suspicious.

8 And for the beginning of the
9 regulations until up to the letter came out
10 from DEA in, I think it was, 2006, 2007 -- as
11 a matter of fact, it was 2007, DEA
12 accepted -- the industry standard was,
13 accepted by DEA -- and they even said in
14 their testimony, depositions, that excessive
15 order reports were fine.

16 Q. And I'm just trying to get an
17 understanding of your interpretation of the
18 law.

19 A. Yeah.

20 Q. So was it your understanding of
21 the law that -- currently, that distributors
22 who routinely report suspicious orders, yet
23 fill those orders without investigating them,
24 are failing to maintain effective controls
25 against diversion?

1 MR. DAVISON: Objection.

2 THE WITNESS: And again, I'll
3 ask to read back what I said
4 previously. It's the same answer.

5 QUESTIONS BY MR. LOESER:

6 Q. So you can't answer that
7 question?

8 MR. DAVISON: Objection.

9 THE WITNESS: I didn't say I
10 can't answer it. I answered the
11 question.

12 QUESTIONS BY MR. LOESER:

13 Q. Are distributors required to
14 know their customers?

15 MR. DAVISON: Objection.

16 THE WITNESS: The registrants
17 that distribute control substances
18 would know their customer base.

19 QUESTIONS BY MR. LOESER:

20 Q. And why should -- why are
21 distributors required to know their
22 customers?

23 MR. DAVISON: Objection.

24 THE WITNESS: Well, it's -- if
25 you want to determine whether an order

1 is suspicious or not, you have to know
2 who you're selling it to or
3 distributing it to, and you want to
4 know certain -- you know, are they
5 registered.

6 QUESTIONS BY MR. LOESER:

7 Q. And what should a distributor
8 do to know its customers?

9 MR. DAVISON: Objection.

10 THE WITNESS: It's outside my
11 scope. Again, it's a hypothetical
12 question as far as I'm concerned.

13 I was retained in order to
14 address Mallinckrodt's program, who is
15 a manufacturer.

16 QUESTIONS BY MR. LOESER:

17 Q. Yet, sir, you testified that
18 you relied on your 50-plus years in the
19 industry to form the opinions you have in
20 this case, so I'm trying to understand your
21 understanding of the law.

22 A. And if you read my opinion
23 based upon -- what I was retained to do,
24 Mallinckrodt.

25 Q. And so, sir, can you answer

1 what your understanding is of what
2 distributors need to do in order to know
3 their customers?

4 MR. DAVISON: Objection.

5 THE WITNESS: 1301.74(b).

6 QUESTIONS BY MR. LOESER:

7 Q. And that's the CSA regulation?

8 A. That's CSA regulation.

9 Q. Anything else? Any other
10 source of requirement?

11 A. It's not a regulatory
12 requirement, but look at the guidance letters
13 put out by DEA in 2006, 2007, 2012.

14 Q. Can a distributor keep shipping
15 controlled substances to a customer whose
16 order it flags as suspicious without first
17 investigating and clearing the flagged order?

18 MR. DAVISON: Objection.

19 THE WITNESS: Again, you're
20 getting into hypothetical questions.

21 I was retained to look at a
22 manufacturer's SOM program. I did no
23 review of any other registrant for
24 this deposition. My report only deals
25 with manufacturer -- for a

1 manufacturer for Mallinckrodt.

2 QUESTIONS BY MR. LOESER:

3 Q. However, you audited a lot of
4 distributor SOM programs in your career,
5 correct?

6 A. Yeah, in my past.

7 Q. And is it your understanding
8 that a -- that a distributor can keep
9 shipping controlled substances to a
10 registrant where it has flagged as suspicious
11 an order to that registrant?

12 MR. DAVISON: Objection.

13 QUESTIONS BY MR. LOESER:

14 Q. Can you keep shipping other
15 orders to that registrant?

16 MR. DAVISON: Objection.

17 THE WITNESS: Again, it's the
18 circumstances. If I was here
19 representing a distributor, I would
20 want to know -- or looking at, I'd
21 want to know all the details
22 associated with the process, anything,
23 just to say, can you keep shipping.

24 What's the -- you know, is that
25 really factual or are they actually

1 doing that or what's the circumstances
2 behind it. Are we talking about a
3 distributor? I want to talk about
4 Mallinckrodt.

5 QUESTIONS BY MR. LOESER:

6 Q. In a distributor's SOM, should
7 the distributor evaluate what particular
8 drugs its customers are ordering?

9 MR. DAVISON: Objection.

10 THE WITNESS: Your SOMs program
11 is looking at all controlled
12 substances. ARCOS looks at only
13 Schedule I and II and Schedule III
14 narcotics unless you're a manufacturer
15 in some other areas. Then you have to
16 report those.

17 That's the requirement. So if
18 you're asking me the requirement,
19 that's the requirement.

20 QUESTIONS BY MR. LOESER:

21 Q. And should the distributor's
22 SOM also evaluate the ratio of controlled
23 substances to noncontrolled substances?

24 MR. DAVISON: Objection.

25 THE WITNESS: There are certain

1 red flags out there, again, not part
2 of the regulations, that you look at
3 in your customer base, depending on
4 who your customer base is.

5 Whether a distributor does all
6 of them or some of them or any -- I --
7 in fact a registrant does some of them
8 or all of them, it's up to the
9 registrant and the customer base they
10 have.

11 QUESTIONS BY MR. LOESER:

12 Q. And what are those red flags?

13 A. Well, in Mallinckrodt's case it
14 would be the distributors, and do you have a
15 registration, do you have appropriate
16 security in place. It would be questions
17 such as that.

18 Q. For a distributor's SOM
19 program, though, when a distributor is
20 operating its SOM, should it evaluate the
21 ratio of controlled substances to
22 noncontrolled substances of its customers?

23 MR. DAVISON: Objection.

24 THE WITNESS: Again, I would
25 say I was hired to look at

1 Mallinckrodt's SOM program.

2 From my past experience, there
3 would be red flags that you could look
4 at depending on the circumstances.
5 One would be cash versus check or
6 insurance. One would be -- and I
7 mentioned this earlier -- do they
8 handle only controlled drugs and no
9 noncontrolled, they don't have any fun
10 items but they're not a medical -- in
11 the medical center where they probably
12 would only handle certain fun items.

13 These are things you would look
14 at, or could look at depending on the
15 circumstances.

16 QUESTIONS BY MR. LOESER:

17 Q. Thank you.

18 Should the distributor's SOM
19 evaluate the location of its customers?

20 MR. DAVISON: Objection.

21 THE WITNESS: Again, I'll
22 repeat myself. Depending on the
23 details, would any registrant -- any
24 type of customers, you make a
25 determination what's good and what's

1 not good, or what you should do -- or
2 what you should look at and not look
3 at or what you need to look at.

4 QUESTIONS BY MR. LOESER:

5 Q. And should the distributor's
6 SOM take into account the number of opioid
7 pills it is sending into one town or county?

8 MR. DAVISON: Objection.

9 THE WITNESS: Again, it's the
10 circumstance behind it. It's -- I
11 can't sit here and just give you
12 general answers.

13 You know, do they have a large
14 hospital in the area? They have a
15 cancer center in the area?

16 Just to say, well, this town,
17 everybody got 10,000 pills, well, is
18 that really true? Did everybody
19 really get 10,000 pills? Or was it
20 high prescribing because they had
21 certain other conditions.

22 QUESTIONS BY MR. LOESER:

23 Q. How does the distributor figure
24 that out? If I understand what you're
25 saying, if there's a distributor that's

1 shipping a large number of pills to one town
2 or county, what due diligence should that
3 distributor do with regard to that county to
4 make sure that the pills aren't being
5 diverted?

6 MR. DAVISON: Objection.

7 THE WITNESS: Any registrant
8 would look at their suspicious order
9 monitoring program, and that's what
10 they should be following.

11 So if I receive an order -- if
12 an order pends based upon the criteria
13 I have in place, I have to make -- I
14 should make a determination if it's
15 suspicious or not and report it to the
16 DEA.

17 What I look at depends on the
18 customer base, the circumstances
19 behind it, who's placing the orders,
20 things like that.

21 QUESTIONS BY MR. LOESER:

22 Q. Do you believe that it would be
23 a red flag for diversion where a distributor
24 is shipping a large number of pills into a
25 small town or county?

1 MR. DAVISON: Objection.

2 QUESTIONS BY MR. LOESER:

3 Q. Something that should be
4 further investigated?

5 MR. DAVISON: Objection.

6 THE WITNESS: Depending on the
7 circumstances, maybe, maybe not.

8 MR. DAVISON: Derek -- I'm
9 sorry, go ahead.

10 THE WITNESS: I'm sorry.

11 MR. DAVISON: No, finish.

12 THE WITNESS: You're giving me
13 hypothetical situations.

14 QUESTIONS BY MR. LOESER:

15 Q. Tell me the circumstances when
16 you think that should be investigated.

17 MR. DAVISON: Objection.

18 THE WITNESS: Again, what's in
19 that area, what's my customer base,
20 who am I shipping to, are there a
21 large concentration of physicians in
22 that given area which would create
23 possibly a spike.

24 I mentioned earlier if there is
25 a cancer institute in there, surgery

1 centers. Is there a lot of surgery
2 centers in that area. I mean, some
3 counties had 10, 15, 20 surgery
4 centers. Well, they had a high
5 consumption of some of the drugs
6 because of the surgical procedures.

7 It depends on a lot of
8 circumstances. Very difficult to
9 answer a question yes or no based on
10 hypothetical situations.

11 QUESTIONS BY MR. LOESER:

12 Q. So the circumstances that you
13 just described, are those things that the
14 distributor should look into when shipping
15 large quantities of pills to a small town or
16 county?

17 MR. DAVISON: Objection.

18 THE WITNESS: Based upon the
19 regulations, a registrant has to take
20 into consideration what the
21 regulations require and also any
22 guidance provided by the Agency.

23 MR. DAVISON: Derek, we've been
24 going about an hour, so we just need
25 to take a break.

1 THE WITNESS: Can we take a
2 break?

3 VIDEOGRAPHER: Going off the
4 record at 2:56 p.m.

5 (Off the record at 2:56 p.m.)

6 VIDEOGRAPHER: We're back on
7 the record at 3:17 p.m.

8 QUESTIONS BY MR. LOESER:

9 Q. Mr. Buzzeo, you've said a
10 number of times when I've asked you questions
11 about the adequacy of a SOM program that it
12 depends on the customer base, the
13 circumstances behind orders and who is
14 placing the orders; is that correct?

15 A. Yes.

16 Q. Can you tell me what
17 investigation you did for Mallinckrodt of its
18 customer base, the circumstances behind
19 orders and who was placing the orders?

20 A. Yes. I looked at the
21 depositions. I looked at the, as I said in
22 my report, all the e-mails and text messages,
23 memoranda, testimony, depositions, as I
24 mentioned earlier, in order to render my
25 opinion.

1 Q. And did you evaluate any
2 information about Mallinckrodt's customer
3 base?

4 A. I looked at the customers that
5 they had, that they were distributors or tier
6 one companies.

7 Q. Did you evaluate specifically
8 who Mallinckrodt's customers were?

9 A. No. I was more interested in
10 how they handle -- or I was retained to look
11 at their -- Mallinckrodt's SOM program and
12 how they handled their orders.

13 Q. And did you evaluate
14 specifically any of Mallinckrodt's orders?

15 A. No. I just looked at their
16 program.

17 Q. And did you evaluate
18 specifically who placed orders to
19 Mallinckrodt?

20 A. No. I just -- how they handled
21 their orders that came in from a customer
22 service representative.

23 Q. And did you evaluate
24 specifically what orders were flagged as
25 suspicious by Mallinckrodt?

1 A. No.

2 Q. And did you --

3 A. Well, I should say a couple --
4 I dealt with a couple of the companies, but
5 more from the process.

6 Q. Okay. And did you evaluate
7 specifically what investigation Mallinckrodt
8 did across the board with orders that it
9 flagged as suspicious?

10 A. I looked at a couple of the
11 reviews, due diligence that they did on a
12 couple of their customers.

13 Q. On a couple of orders?

14 A. Uh-huh. A couple of their
15 customers.

16 Q. And yet notwithstanding what
17 you did not review from Mallinckrodt, you
18 were able to provide an opinion on whether
19 you believed Mallinckrodt's SOM and
20 anti-diversion programs were adequate?

21 MR. DAVISON: Objection.

22 THE WITNESS: Based upon what I
23 looked at, the records, the various
24 depositions, the reports, I was able
25 to render the decision that they met

1 the regulatory requirements, and also
2 guidance from the Agency.

3 QUESTIONS BY MR. LOESER:

4 Q. And what particular customers
5 of Mallinckrodt's did you evaluate?

6 MR. DAVISON: Objection.

7 THE WITNESS: I looked at how
8 they handled KeySource, Sunrise, I
9 think Masters.

10 QUESTIONS BY MR. LOESER:

11 Q. And why those customers?

12 A. Because their -- I was provided
13 those. I asked, what customers did you
14 have -- did you do some due diligence on.

15 I do know that they met with
16 some of the big three distributors to discuss
17 programs and possible pharmacies.

18 Q. Earlier you stated that the
19 fact that an order is triggered as suspicious
20 by an algorithm is not enough to report the
21 order as suspicious to the DEA.

22 Do you recall that testimony?

23 MR. DAVISON: Objection.

24 Misstates his testimony.

25 THE WITNESS: I believe what I

1 said was, as, as an order is pend, you
2 should review it to determine if it's
3 suspicious or not suspicious.

4 QUESTIONS BY MR. LOESER:

5 Q. And what is the basis for that
6 conclusion?

7 A. Well, first of all, the
8 regulation talks about reporting suspicious
9 orders. You have to make a determination
10 whether an order is suspicious or not.

11 To me, an algorithm in itself
12 is not enough. As far as I'm concerned,
13 based upon my vast experience, an algorithm
14 just tells you, here's something you should
15 look at further.

16 Q. And so if a DEA registrant
17 doesn't do any further investigation, does
18 that mean it doesn't have to report anything
19 to the DEA?

20 MR. DAVISON: Objection.

21 THE WITNESS: The regulation
22 says you have to report suspicious
23 orders. So if -- you have to make a
24 determination whether the order is
25 suspicious or not. How you do that is

1 up to you.

2 QUESTIONS BY MR. LOESER:

3 Q. So if you don't do anything and
4 you don't do any investigation, you don't
5 have to report anything to the DEA?

6 A. No.

7 MR. DAVISON: Objection.

8 THE WITNESS: Then it's
9 possible, it's possible, that order
10 may be suspicious. It's possible it's
11 not suspicious.

12 You got -- the requirement is
13 you have to report suspicious orders
14 to DEA.

15 QUESTIONS BY MR. LOESER:

16 Q. Sir, have you ever advised your
17 DEA registrant clients that they should
18 complete the investigation of orders flagged
19 as suspicious before shipping the orders?

20 A. In order to make a
21 determination, you have to do due diligence
22 on an order that pends to determine if it's
23 suspicious or not suspicious.

24 The requirement is if the order
25 is suspicious, you should report -- you have

1 to report it to DEA. Then you have to make a
2 determination of ship, don't ship.

3 We've talked clients in the
4 past, if you make that determination, you
5 probably should not ship it until you do a --
6 further reviews and looking at the -- your
7 possible customer.

8 Q. Okay. I want to try again and
9 make sure I understand.

10 Have you ever actually advised
11 your DEA registrant clients that they should
12 complete the investigation of orders flagged
13 as potentially suspicious before shipping the
14 orders?

15 MR. DAVISON: Objection. Asked
16 and answered.

17 THE WITNESS: We advise clients
18 to make a determination, do the due
19 diligence, make a determination if the
20 order is suspicious, not suspicious,
21 and report it to the DEA if it is
22 suspicious.

23 QUESTIONS BY MR. LOESER:

24 Q. And when did you start advising
25 your clients of that?

1 A. Oh, probably 2000.

2 Q. And have you ever advised --

3 A. Or probably -- yeah, 2000 --
4 when did I retire?

5 Yeah, when I first started the
6 company and working with various clients.

7 Q. Have you ever advised your DEA
8 registrant clients to report orders to the
9 DEA that cannot be cleared of suspicion and
10 cancel the entire order?

11 MR. DAVISON: Objection.

12 THE WITNESS: Give me that
13 question again.

14 QUESTIONS BY MR. LOESER:

15 Q. Have you ever advised your DEA
16 registrant clients to report orders to the
17 DEA that cannot be cleared of suspicion and
18 cancel the entire order?

19 MR. DAVISON: Objection.

20 THE WITNESS: The last part,
21 when you put in "the entire order," so
22 are you saying that the order comes
23 in, they look at, say, "Well, this one
24 drug is suspicious," but ship the rest
25 of it?

1 QUESTIONS BY MR. LOESER:

2 Q. No, I'm asking you if you've
3 ever advised your clients to report to the
4 DEA orders that cannot be cleared of
5 suspicion and cancel the order.

6 MR. DAVISON: Objection.

7 QUESTIONS BY MR. LOESER:

8 Q. Does that make sense?

9 Have you ever advised your DEA
10 registrant clients to report orders to the
11 DEA that your clients have done due diligence
12 on, can't clear, and cancel the order?

13 MR. DAVISON: Objection.

14 THE WITNESS: If the order is
15 suspicious -- we would tell them, if
16 your order is suspicious, you have to
17 report to DEA.

18 So if a pended order is
19 suspicious, you report it to DEA.

20 If you do due diligence and
21 it's not suspicious, then you don't
22 have to report it.

23 Is that the question?

24 QUESTIONS BY MR. LOESER:

25 Q. And when do you advise your

1 clients they have to cancel an order and
2 report it to the DEA?

3 MR. DAVISON: Objection.

4 THE WITNESS: Well, what I say
5 to DEA -- what I say to DEA, if it's
6 suspicious, you report to DEA.

7 You have to make a
8 determination based upon the facts you
9 have whether you should ship it or not
10 ship. Regulation doesn't cover that.

11 And DEA will probably -- in
12 some cases I've heard the DEA has
13 already told clients that: We can't
14 tell you to ship it or not ship it.
15 Your requirement is to tell us the --
16 you know, the report as far as if it's
17 suspicious. If it turns out it's
18 diverted, you shipped it, we very well
19 may come after you.

20 QUESTIONS BY MR. LOESER:

21 Q. Okay. Have you ever told your
22 clients if they can't clear a suspicious
23 order that they should cancel an order?

24 MR. DAVISON: Objection. Asked
25 and answered.

1 THE WITNESS: We tell our
2 clients that they have to meet the
3 regulatory requirement. If it's
4 suspicious, you have to report it.

5 So if an order pends, you have
6 to make a determination. And if it's
7 suspicious, you have to report it to
8 DEA.

9 I don't recall any
10 circumstances that you're talking
11 about where if you can't pend -- you
12 can't determine one way or the other,
13 just to go ahead and ship it. I'd
14 probably recommend, better talk to
15 DEA. Maybe you should go out and do
16 an on site if you haven't done that.
17 Go further on the order so you can
18 make that determination.

19 QUESTIONS BY MR. LOESER:

20 Q. Have you ever advised your
21 clients that they should cancel orders that
22 they can't clear of suspicion?

23 MR. DAVISON: Objection. Asked
24 and answered four times.

25 THE WITNESS: If an order is

1 canceled and there's a reason why you
2 cancel it, if it's suspicious, you
3 better report it to DEA. If you
4 cancel because you don't have
5 sufficient facts, you'd better go out
6 and do a further due diligence.

7 QUESTIONS BY MR. LOESER:

8 Q. I'm asking you a pretty simple
9 but different question.

10 Have you ever advised your
11 clients that if they can't clear the
12 suspicions for an order, that they should
13 cancel the order?

14 MR. DAVISON: Objection. Asked
15 and answered five times.

16 THE WITNESS: If -- go back to
17 the regulation. If the order is
18 suspicious, you report it to DEA. If
19 the order is not suspicious, you don't
20 report it to DEA.

21 If you cannot make a
22 determination, we advise the client,
23 go out and do more due diligence. You
24 want us to do it for you, you want to
25 do it, you want to hire somebody to do

1 it, you want to do it yourself, send
2 your security people out to the firm,
3 you have to make a determination.

4 QUESTIONS BY MR. LOESER:

5 Q. So you've never actually
6 advised your clients that they should cancel
7 orders where they haven't been able to clear
8 the suspicion?

9 A. That's the answer I have.

10 MR. DAVISON: Objection. Asked
11 and answered six times.

12 QUESTIONS BY MR. LOESER:

13 Q. You haven't ever advised your
14 clients of that?

15 MR. DAVISON: Objection.

16 THE WITNESS: We advise our
17 client that if the order is
18 suspicious, report it. If the order
19 is not suspicious after you do your
20 due diligence, go ahead and ship it.

21 If you cannot make a
22 determination based upon the facts
23 that you've used, go out -- let's say
24 you haven't gone on site. Go on site
25 and make that determination. Look at

1 it in depth, but make a determination.

2 Because if you're canceling the
3 order, there's a reason why you
4 canceled it. If you're shipping the
5 order and you haven't made that
6 determination, then you could be
7 running into issues.

8 QUESTIONS BY MR. LOESER:

9 Q. And what do you mean by
10 "issues"?

11 A. Well, if it's a suspicious
12 order, you haven't met the regulatory
13 requirement.

14 Q. And so if an order is flagged
15 by the SOM as suspicious, is the default then
16 that it's suspicious until due diligence
17 clears it?

18 A. To me --

19 MR. DAVISON: Objection.

20 THE WITNESS: I'm sorry.

21 To me an order, when it's
22 flagged, does not necessarily mean
23 it's suspicious. You have to do your
24 due diligence on it.

25 You can't use one criteria to

1 say, hey, it's flagged, it's exceeded
2 a certain number, it's suspicious.

3 As I gave examples earlier, I
4 could have a doctor or a pharmacy
5 ordering a thousand dosage units,
6 nothing flags it, but it turns out to
7 be the person's diverting.

8 If I have a number of 8,000 and
9 it exceeds that, it may not be
10 suspicious.

11 So I like the terminology
12 better, it flagged, it's probably --
13 it's something that should be looked
14 at further. So let's call it
15 excessive. Let's call it peculiar.
16 Let's call it something. And then you
17 make your determination whether it's
18 suspicious or not.

19 QUESTIONS BY MR. LOESER:

20 Q. So due diligence is required on
21 all orders flagged as suspicious?

22 A. Some form --

23 MR. DAVISON: Objection.

24 THE WITNESS: Either customer
25 sales reps are involved in it,

1 security is involved in it,
2 somebody -- you're looking at all the
3 facts involved with that. You're
4 having discussions with the customer,
5 you may have a questionnaire, whatever
6 you're looking at to make that
7 determination. And if it's
8 suspicious, then you'd better report
9 it.

10 QUESTIONS BY MR. LOESER:

11 Q. Have you ever advised your DEA
12 registrant clients that they should not
13 reduce an order that exceeds size thresholds
14 to the threshold limit and then ship the
15 reduced order?

16 MR. DAVISON: Objection.

17 THE WITNESS: I've never
18 advised a client on that. I would
19 advise a client not to do that.

20 QUESTIONS BY MR. LOESER:

21 Q. When did you start advising
22 your clients not to do that?

23 A. Probably right from the -- I
24 don't recall when, but it's probably close to
25 when I started the company.

1 To me the whole order is
2 suspicious, not just one item in the order.

3 Q. Have you ever advised your DEA
4 registrant clients that it's important for
5 them to know their customers?

6 MR. DAVISON: Objection.

7 THE WITNESS: Well, you want to
8 know your customer base from a
9 regulatory perspective, from a
10 financial perspective, before you
11 establish them as a client -- a
12 customer and also to maintain them as
13 a customer.

14 QUESTIONS BY MR. LOESER:

15 Q. And when did you start advising
16 your clients that it's important for them to
17 know their customers?

18 MR. DAVISON: Objection.

19 THE WITNESS: Well, the
20 regulations address it, too. You
21 know, you're verifying the
22 registration, and you're probably
23 doing a Dun & Bradstreet on them,
24 probably doing a financial on them,
25 you know, to determine if the customer

1 is legit, is real.

2 QUESTIONS BY MR. LOESER:

3 Q. And when did you start advising
4 your clients?

5 A. Right from the beginning.

6 Q. Okay. And have you ever
7 advised your manufacturer clients they need
8 to know their customers' customers?

9 MR. DAVISON: Objection.

10 THE WITNESS: No. Not that I
11 recall.

12 What I would advise them is you
13 have -- the regulation talks about
14 your customer -- your registration,
15 and when you ship to your customer
16 that the responsibility switches to
17 them.

18 There could be circumstances
19 when you find out about something that
20 you want to look at. And that's what
21 Mallinckrodt did with their chargeback
22 program.

23 QUESTIONS BY MR. LOESER:

24 Q. Have you ever advised your
25 distributor clients that they should evaluate

1 what their customers do with controlled
2 substances they purchase from your client?

3 MR. DAVISON: Objection.

4 THE WITNESS: Again, I'm in a
5 better position to talk about
6 Mallinckrodt's program than I am the
7 wholesaler's program. Then we're
8 going to get back into hypothetical
9 questions.

10 And as I've stated on numerous
11 occasions, it has to do with the
12 customer base, the circumstances, the
13 drugs you're handling.

14 QUESTIONS BY MR. LOESER:

15 Q. And I'm asking you a very
16 specific question.

17 Have you ever advised your
18 distributor clients that they should evaluate
19 what their customers do with the controlled
20 substances they purchase from your client?

21 MR. DAVISON: Objection.

22 THE WITNESS: We advise
23 registrants that -- to look at their
24 customer base from a number of
25 perspectives, you know, from a

1 regulatory perspective and
2 registration, SOM, things like that.

3 QUESTIONS BY MR. LOESER:

4 Q. When did you start advising
5 your distributor clients that they should
6 evaluate what their customers do with
7 controlled substances they purchase from the
8 distributor?

9 MR. DAVISON: Objection.

10 THE WITNESS: From the
11 beginning, we would advise our clients
12 on the requirements of the regulations
13 and that the regulations -- you know,
14 here's some recommendations how to
15 meet those regulatory requirements
16 from a regulatory perspective.

17 QUESTIONS BY MR. LOESER:

18 Q. And did that include -- did the
19 regulations include requiring distributors to
20 know what their customers did with the
21 controlled substances they purchased from
22 distributors?

23 A. Again, I'm going to refer --

24 MR. DAVISON: Objection.

25 THE WITNESS: I'm going to

1 refer to my manufacturer client and --
2 and I should say or registrants, that
3 if you're going to be in the
4 controlled substance business, that
5 these are regulatory requirements, and
6 here's the industry standards, and
7 this is what you have to meet.

8 And I found the -- almost every
9 one of the -- I should say probably
10 99.9 percent of the legitimate
11 industry wants to meet the regulatory
12 requirements, probably has limited
13 guidance. So you have to depend on
14 your knowledge, the knowledge of the
15 industry standards and things like
16 that.

17 QUESTIONS BY MR. LOESER:

18 Q. Is a DEA registration that has
19 had its license to distribute controlled
20 substances revoked part of a legitimate
21 industry?

22 MR. DAVISON: Objection.

23 THE WITNESS: It really depends
24 on the circumstances, why was it
25 revoked.

1 QUESTIONS BY MR. LOESER:

2 Q. If a DEA registrant has its
3 licensed revoked by the DEA because it
4 enabled diversion, do you consider that
5 registrant to have been part of the
6 legitimate industry?

7 MR. DAVISON: Objection.

8 THE WITNESS: Well, you know,
9 there's registrant -- it depends on
10 the circumstances behind it.

11 If they have their registration
12 revoked because of a diversion issue,
13 that's an issue.

14 QUESTIONS BY MR. LOESER:

15 Q. Does that make them not part of
16 the legitimate industry?

17 A. Yeah.

18 MR. DAVISON: Objection.

19 QUESTIONS BY MR. LOESER:

20 Q. Have you ever advised your
21 manufacturer clients that they should
22 evaluate what their distributor customers do
23 with controlled substances they purchase from
24 a manufacturer?

25 MR. DAVISON: Objection.

1 THE WITNESS: That's getting
2 back to the issue of know your
3 customer's customer. There's no
4 regulatory requirement for that. It's
5 extremely difficult.

6 However, like in Mallinckrodt's
7 case, they were able to use the
8 chargeback program in some of the --
9 some issues, not necessarily a
10 diversion issue but some issues where
11 they would stop -- they told the
12 wholesalers that they would not honor
13 chargeback requests or -- and they
14 reported to DEA and the entire
15 distribution chain.

16 QUESTIONS BY MR. LOESER:

17 Q. And what I asked you was
18 whether you advised your manufacturer clients
19 that they should evaluate what their
20 distributor customers do with controlled
21 substances purchased from the manufacturer.

22 MR. DAVISON: Objection.

23 QUESTIONS BY MR. LOESER:

24 Q. That's the customer of the
25 manufacturer.

1 A. I know. It's the customer's
2 customer.

3 MR. DAVISON: Objection.

4 QUESTIONS BY MR. LOESER:

5 Q. No, not the customer's
6 customer.

7 A. You said the --

8 Q. The wholesaler distributor is
9 the customer of the manufacturer, right?

10 A. The wholesale distributor is
11 the customer of the manufacturer.

12 Q. Right.

13 Have you ever advised your
14 manufacturer clients that they need to know
15 what their wholesale distributor customers do
16 with the drugs they purchase from the
17 manufacturer?

18 A. The way I'm interpreting
19 that --

20 MR. DAVISON: Objection.

21 THE WITNESS: -- is that you're
22 asking me about a customer's customer.
23 And that's extremely difficult.

24 But in Mallinckrodt's
25 situation, they have looked at -- to a

1 chargeback program and also working
2 with their whole -- some of their
3 wholesalers to identify pharmacies and
4 look at those pharmacies.

5 QUESTIONS BY MR. LOESER:

6 Q. Have you ever advised your
7 manufacturer clients that they should utilize
8 chargeback data in order to better understand
9 what their distributor clients do with the
10 controlled substances they purchase from
11 manufacturers?

12 MR. DAVISON: Objection.

13 THE WITNESS: Chargeback --
14 chargebacks -- first of all, it's not
15 a regulatory requirement. Understand
16 that.

17 Chargebacks are a financial
18 issue -- a financial program. It's
19 always in finance. It had to do with
20 the pricing, contractual arrangements
21 between the -- let's say the
22 wholesaler and the type of clients
23 they have or if the manufacturer was
24 shipping directly, and it would be a
25 reimbursement to make up for the

1 difference in pricing.

2 So like I said, not a
3 regulatory requirement. It's always
4 been a financial report.

5 When Mallinckrodt -- in one of
6 their reviews, their finance
7 department was able to do a study --
8 and this is rare. They probably --
9 they're probably one of the first
10 companies to do this. And even DEA
11 said it was a standard for the
12 industry -- looked at their chargeback
13 data in one of the reviews they did,
14 and they saw that it did help them,
15 and now they have a chargeback as part
16 of their program.

17 QUESTIONS BY MR. LOESER:

18 Q. And, sir, I'm asking you again
19 a very specific question.

20 Have you ever advised your
21 manufacturer clients that they should utilize
22 chargeback data in order to better understand
23 what their distributor clients do with
24 controlled substances they purchase from
25 manufacturers?

1 So I'm asking about the
2 advice --

3 A. Yeah.

4 Q. -- whether you have given that
5 advise to your clients.

6 MR. DAVISON: Objection.

7 THE WITNESS: I understand.

8 And this is probably my later
9 years with the company, but once we
10 became aware of it, depending on the
11 client, the customer or the registrant
12 and their customer base and what they
13 were actually -- you know, had to
14 market, they were dealing in, we said,
15 one of the things you may want to look
16 at is the chargeback data.

17 It's may not -- it's after the
18 fact. It's not an order, but it's
19 very possible it may give you some
20 issues that DEA may want -- or some,
21 let's say, issues that DEA may want to
22 look at, and we described to them what
23 the industry was doing.

24 And that's what Mallinckrodt
25 did.

1 QUESTIONS BY MR. LOESER:

2 Q. And when did you start
3 advising --

4 A. And Mallinckrodt, like I said,
5 DEA said they set the standard in the
6 industry.

7 Q. When did you start advising
8 your manufacturer clients to use chargeback
9 data?

10 MR. DAVISON: Objection.

11 THE WITNESS: As you know,
12 chargeback data was a financial thing.
13 It was done mainly for pricing.

14 Once the industry found out
15 about it, once we found out about it,
16 we said, geez, something, depending on
17 the registrant we're dealing with, we
18 want to -- we may want to recommend
19 that they look at it as a possible --

20 QUESTIONS BY MR. LOESER:

21 Q. And when did you start giving
22 that advice?

23 A. Remember, it's not a regulatory
24 requirement.

25 Q. When did you start giving that

1 advice?

2 A. I don't recall.

3 Q. You don't have any idea?

4 A. Excuse me?

5 Q. You have no idea?

6 A. No, it's probably like -- I
7 don't recall.

8 Q. Have you ever advised a DEA
9 registrant client to stop shipping to certain
10 types of downstream customers like pain
11 clinics?

12 MR. DAVISON: Objection.

13 THE WITNESS: We would tell
14 them -- now, I'm recalling this. We
15 would tell them to be very careful
16 with the down -- if they were pain
17 clinics, and you better look at it
18 very carefully. Just like we would
19 tell them as part of our due
20 diligence, Internet pharmacies, if
21 they're an Internet pharmacy, you
22 better look at it very carefully, that
23 it's legit.

24 QUESTIONS BY MR. LOESER:

25 Q. And why did you tell your

1 clients to look very carefully at pain
2 clinics?

3 MR. DAVISON: Objection.

4 THE WITNESS: Because of the
5 information we had that some of them
6 were not meeting the regulatory
7 requirements and actually were
8 diverters. And just like some of the
9 Internet pharmacies were not meeting
10 some of the requirements and actually
11 they were diverting, let's say for
12 nonmedical uses, into the trade.

13 And DEA looked at that and
14 put -- my understanding is put a lot
15 of resources into Internet pharmacies
16 and pain clinics.

17 QUESTIONS BY MR. LOESER:

18 Q. And when did you start advising
19 your DEA registrant clients to look very
20 carefully at pain clinics and Internet
21 pharmacies?

22 A. I don't -- I don't recall.

23 Q. You have no idea?

24 A. I don't recall. You know, it's
25 been a long career dealing with a lot of

1 different clients and customers and different
2 issues, business issues and due diligence,
3 that I don't recall all the dates.

4 Q. Have you ever advised any of
5 your DEA registrant clients to implement
6 rules to prevent orders that are suspicious
7 on their face from being shipped?

8 MR. DAVISON: Objection.

9 THE WITNESS: We would advise
10 our clients that the regulations said,
11 and if the order is suspicious, report
12 it to DEA. And make sure you do good
13 due diligence and that you probably --
14 you know, then you got to make a
15 determination ship/don't ship.

16 And if you made a determination
17 that it's suspicious, report it to the
18 DEA, be careful if you ship it.

19 QUESTIONS BY MR. LOESER:

20 Q. What were the characteristics
21 that would make an order suspicious on its
22 face?

23 MR. DAVISON: Objection.

24 THE WITNESS: What the
25 regulation says. Well, I shouldn't

1 say that. The regulation is giving
2 you things that you should look at so
3 the order would pend, or you would
4 stop it to make a determination if
5 it's suspicious. Because the
6 regulation just says report suspicious
7 orders. We have to make some
8 determination if it's suspicious.

9 The DEA is giving you a hint --
10 or the regulation is giving you a hint
11 to talk about pattern, you know,
12 orders of size, and that's a starting
13 point to me.

14 What you got to look at then is
15 type of customer that they're shipping
16 to, what are the circumstances, is it
17 an institution, is it a major
18 hospital. Those are the things you'd
19 look at in making a determination
20 whether it is suspicious or not.

21 If it's a pharmacy you're
22 looking at, you know, if you decide to
23 do -- and especially an independent
24 pharmacy, you decide to do an on-site
25 review of it, you'd list some of the

1 things you look at, you know, long
2 lines, out of state.

3 QUESTIONS BY MR. LOESER:

4 Q. And so after all of your years
5 in the industry, is there a list -- a set of
6 characteristics that you can identify that
7 would -- that would indicate that an order is
8 suspicious on its face?

9 A. There's things that -- like red
10 flags you're referring to earlier that you
11 could look at.

12 Q. And you talked about some red
13 flags.

14 Are there others that come to
15 mind that would make an order suspicious on
16 its face?

17 A. Well, it's red flags that you
18 would look at that say, yeah, this could be
19 suspicious. We may want to look further.

20 Q. What about not could be
21 suspicious but suspicious on its face?

22 A. Well, to make a -- it's very
23 difficult to say on its face that it's
24 suspicious. Like I said, if you have a fixed
25 program and you set a fixed number, let's

1 say, of 10,000 or 15,000, just because it
2 exceeds that doesn't make it suspicious.
3 It's something you should look further at.

4 Q. So you're saying that you
5 haven't used the expression "suspicious on
6 its face" before when advising your clients?

7 MR. DAVISON: Objection.

8 THE WITNESS: I could advise
9 them, you have to report suspicious
10 orders in that -- an order when it
11 pends in your system. Whether it's a
12 paper-based system or electronic
13 system, you have to make a
14 determination. You have to look
15 further and do your due diligence.

16 Again, that due diligence is
17 based on the type of registrant
18 whether the order is suspicious or
19 not.

20 QUESTIONS BY MR. LOESER:

21 Q. When you were with BuzzeoPDMA,
22 did the company market SOM programs that
23 clients could purchase and utilize to detect
24 suspicious orders?

25 A. Yes.

1 Q. And did any companies purchase
2 those programs?

3 MR. DAVISON: Objection.

4 THE WITNESS: I would believe
5 so. Otherwise I wouldn't have been
6 selling it.

7 QUESTIONS BY MR. LOESER:

8 Q. Do you recall which companies
9 purchased those programs?

10 A. No.

11 Q. Can you explain how those
12 programs operated?

13 A. Not really. My main role
14 was -- is from a regulatory perspective. We
15 would discuss -- statisticians would sit down
16 with us and discuss the regulatory issues as
17 we would have an attorney in the room, and
18 that's how it was done.

19 And again, I wouldn't say
20 that -- there's no system that fits
21 everybody's needs. So I may go in to a
22 client and say, this is not what you want. I
23 would recommend this.

24 So but my role in it was just
25 from a regulatory perspective.

1 Q. Do you know if the SOM program
2 that BuzzeoPDMA marketed contained a SOM
3 algorithm?

4 A. It contained a threshold. How
5 that was put together, you'd have to ask the
6 statisticians.

7 Q. Do you have any -- do you
8 recall --

9 A. But again -- let me clarify
10 this -- that didn't mean it was suspicious
11 when it pend. An order pend, as any system
12 would, that tells you you should relook at
13 it.

14 And again, when you're
15 implementing a system, any system, it takes a
16 lot of time to revise it so it fits your
17 model, your customer base. So it's not a
18 system you put in place today and say it's
19 functioning. It's functioning, but it
20 doesn't mean that it doesn't need to be
21 adjusted over time as more and more data
22 enters the program. That's with any of them,
23 any good system.

24 Q. What do you recall about the
25 threshold that the BuzzeoPDMA SOM program

1 utilized?

2 A. I have no idea. I don't
3 recall.

4 Q. Is that something that would
5 be, you know, in a written marketing proposal
6 to any of your clients?

7 A. I don't know. My only area of
8 expertise in that was from a regulatory
9 perspective and what it had to do in
10 reporting to DEA.

11 Q. And was it your understanding
12 that the algorithm used in the BuzzeoPDMA SOM
13 program could be tailored for the particular
14 needs of customers that would buy that
15 program?

16 A. My understanding was -- is when
17 a customer -- that program took -- could take
18 time in order to accumulate a database in
19 order to fit that customer or that
20 registrant.

21 Q. Do you know if the BuzzeoPDMA
22 SOM program utilized any type of basic
23 formula for identifying orders of unusual
24 size?

25 A. I don't know the details on how

1 it identified excessive orders or orders to
2 pend.

3 Q. Is it your recollection when
4 the BuzzeoPDMA SOM program -- if an order
5 pinged as suspicious, that then due diligence
6 was necessary on that order?

7 A. It pend as -- my understanding
8 is it pend as excessive, and then a
9 determination was made whether it was
10 suspicious or not.

11 Q. And how would that
12 determination be made?

13 A. Through due diligence.

14 Q. And did that determination need
15 to be made before the order could be shipped?

16 MR. DAVISON: Objection.

17 THE WITNESS: That's a deter --
18 the company would have to make a
19 determination, first of all, is it
20 suspicious, and then they report it to
21 DEA. Then the determination is made
22 to ship/don't ship.

23 QUESTIONS BY MR. LOESER:

24 Q. And that's how the BuzzeoPDMA
25 SOM program operated?

1 MR. DAVISON: Objection.

2 THE WITNESS: No. The system
3 would just pend orders that need to be
4 looked at to determine if they were
5 suspicious.

6 QUESTIONS BY MR. LOESER:

7 Q. Turn back to your report.

8 A. Okay.

9 Q. On page 3 of your report, Roman
10 Numeral III, summary of opinions,
11 paragraphs 22 through 27 --

12 A. 22 through 27?

13 Q. Yeah.

14 -- summarize six opinions.

15 Are those the six opinions that
16 you're providing in this case that are listed
17 under that summary?

18 A. Yes.

19 Q. And these opinions are the
20 result of the work that you did in this
21 engagement?

22 A. Yes.

23 Q. And are you going to be
24 providing any other opinions in this case
25 other than those six?

1 A. At this time, I don't know. I
2 left it saying that I may end up amending
3 or -- depending if more information becomes
4 available. But for right now, this is my
5 opinion on the program, and I really have no
6 reason to change it.

7 Q. And you haven't been asked to
8 provide any other opinions?

9 A. No, not at this point.

10 Q. By Mallinckrodt?

11 A. Not at this -- well, I've been
12 dealing with Ropes & Gray. No, not at this
13 point.

14 Q. Okay. And no other defendant
15 or counsel has asked you to provide any
16 opinions?

17 A. No, sir.

18 You know, I clarify. I've been
19 only retained by Ropes & Gray on behalf of
20 Mallinckrodt.

21 Q. And you have no intention of
22 testifying at trial as to any opinions other
23 than those six that are provided in your
24 report?

25 MR. DAVISON: Objection.

1 THE WITNESS: At this time.

2 QUESTIONS BY MR. LOESER:

3 Q. Are you aware of any aspects of
4 your opinion that you may supplement in the
5 future?

6 A. Not at this point.

7 Q. On paragraph 55 of your report,
8 the second sentence states, "The
9 anti-diversion language of the CSA has not
10 changed since 1971, nor has the suspicious
11 order monitoring regulation."

12 A. Yes.

13 Q. Did you write that sentence?

14 A. Yes.

15 Q. And do you believe that to be
16 true?

17 A. Yes.

18 Q. In paragraph 61 you state,
19 "Neither the CSA, nor any of the implementing
20 regulations, defines the term 'unusual
21 size.'"

22 Do you see that?

23 A. Yes.

24 Q. What's your understanding of
25 the terms -- and the paragraph actually goes

1 on and notes, "The DEA has not defined
2 unusual size, frequency or pattern."

3 What's your understanding of
4 those terms?

5 MR. DAVISON: Objection.

6 THE WITNESS: What I said here,
7 number one, is they haven't defined
8 the term, so in my opinion it would
9 be -- you'd have to look at -- again,
10 I get back to this -- your customer
11 base. Average order size you may look
12 at, the types of drugs, in order to
13 determine, you know, what's unusual a
14 size. Is for a pharmacy 10,000 pills
15 unusual, anything over that for a
16 distributor? Is it a million pills,
17 that's unusual size?

18 Normal pattern. Is a normal
19 pattern for this particular customer
20 they were ordering once a month, now
21 all of a sudden they're ordering twice
22 a month?

23 Frequency is also -- maybe
24 instead of every two days, they're
25 ordering every day.

1 So it really depends. It
2 depends -- basically the regulation
3 allowed the industry, or the
4 registrant who has this requirement,
5 to determine what is unusual to them,
6 what's pattern, what's frequency.

7 I think that, in my opinion, is
8 what the regulation intended. There
9 was no way to set a standard. Let the
10 industry determine what -- how they
11 should implement this regulatory
12 requirement.

13 That's why I said earlier, one
14 system doesn't fit everybody's needs.

15 QUESTIONS BY MR. LOESER:

16 Q. And you haven't, in all of your
17 work in the industry, haven't tried to come
18 up with some metrics that you can utilize to
19 guide your clients on what those terms means?

20 A. No.

21 MR. DAVISON: Objection.

22 QUESTIONS BY MR. LOESER:

23 Q. If you turn to paragraph 72 of
24 your report.

25 A. 72.

1 Q. You note that "some registrants
2 have explored the question of how they might
3 use alternative data sources like downstream
4 transactional data to address specific
5 instances of potential downstream diversion
6 that they become aware of."

7 Do you see that?

8 A. Yes.

9 Q. And that's chargeback data that
10 you're referring to there?

11 A. Yeah, that's chargeback data.

12 Q. And this exploration that
13 you're referring to here of those data
14 sources, is it your understanding that that's
15 something that some registrants did at --
16 just on their own, at their own behest?

17 A. To utilize the chargeback data?

18 Q. Yeah.

19 A. Yes. And Mallinckrodt first
20 started that on their own when they had a
21 situation with -- I think it was some
22 Tennessee investigation or something from
23 local police, and they utilized that in order
24 to determine something that needed to be
25 looked at further. And that's how they begun

1 to use the chargeback data.

2 Because you remember I said
3 earlier, or I'm sure other people have said,
4 chargeback data is a financial report. It
5 was always considered a financial report,
6 always had to do with reimbursement because
7 of the different client bases.

8 Q. If you turn to paragraph 82.

9 A. Excuse me, 83?

10 Q. 82.

11 A. 82.

12 Q. You indicate in this paragraph
13 that "the goal of reporting excessive
14 purchases was to provide DEA with information
15 that the Agency could use to determine
16 whether to investigate certain registrants."

17 A. Yes.

18 Q. "The industry standard at the
19 time was to provide this information to DEA,
20 and then it was DEA, not the manufacturer,
21 who was responsible for undertaking any
22 investigation of purchases reflected on
23 excessive purchase reports."

24 Do you see that?

25 A. The industry standard -- yes.

1 Q. And this paragraph is in the
2 section that you've described as 1998 through
3 2007; is that correct?

4 A. Correct.

5 Q. And there's no citation to this
6 paragraph for -- or any materials cited.

7 What's the basis for that
8 statement?

9 MR. DAVISON: Objection.

10 THE WITNESS: The basis of that
11 statement is that based upon my
12 experience, is the industry from the
13 early days till the first letter came
14 out, I guess it was 19 -- December
15 2007, was providing excessive reports
16 that they would print out and provide
17 these to DEA, basically as a tool for
18 DEA use for possible -- identifying
19 possible targets for investigation or
20 further investigation. And this went
21 on through the vast majority of the
22 industry, I would assume.

23 And the DEA finally, after that
24 letter came out -- like in
25 Mallinckrodt's case, St. Louis says,

1 "Hey, you know, thank you, but we
2 don't need these any longer." We've
3 seen the new guidance.

4 And that's when I said it was a
5 standard of change. It really was a
6 big change to the industry, after all
7 these years to be told what we've been
8 doing, we don't want them anymore.

9 QUESTIONS BY MR. LOESER:

10 Q. And does paragraph 82
11 accurately reflect the guidance you gave your
12 clients in the 1998 through 2007 time period?

13 MR. DAVISON: Objection.

14 THE WITNESS: Well, what else
15 we would tell them -- now this is what
16 was going on in the industry. We'd
17 also tell them that, remember now, on
18 suspicious orders you have to report.

19 QUESTIONS BY MR. LOESER:

20 Q. Right.

21 But you told them that they
22 were to report suspicious orders to the DEA,
23 but it was the DEA, not the manufacturer, who
24 was responsible for undertaking any
25 investigation of purchases reflected on the

1 excessive purchase reports.

2 That's guidance that you
3 provided to your clients in that time period?

4 A. It's guidance that, you know,
5 that industry, companies are supplying,
6 monthly, quarterly basis, these printouts of
7 excessive orders, what was considered
8 excessive orders, providing that to DEA.

9 The intention was that DEA
10 would use this as possible investigative
11 targets, not necessarily but could, and
12 that -- but you still had the requirement to
13 report suspicious orders.

14 But this was the standard in
15 the industry and accepted by DEA until the
16 letter came out. So DEA -- this is what DEA
17 was getting. This is what DEA expected.

18 Q. And all I'm trying to
19 understand, sir, is whether that standard
20 that you've described in paragraph 82, is
21 that the guidance that you provided to your
22 clients between the time frame 1998
23 through 2007?

24 MR. DAVISON: Objection.

25 THE WITNESS: Well, if --

1 QUESTIONS BY MR. LOESER:

2 Q. With regard to that standard.

3 A. Yeah. This section, we would
4 tell them it was an industry standard and
5 this is what industry was using. As a new
6 registrant, this is what was being done, but
7 we also explained to them the regulatory
8 requirement.

9 Q. And --

10 A. And this was, again, accepted
11 by DEA.

12 Q. And so you told your clients
13 that after they reported the order, they
14 didn't have further obligation to investigate
15 those orders, but instead it was the DEA that
16 did that?

17 MR. DAVISON: Objection.

18 THE WITNESS: What we said was,
19 is you're reporting excessive orders,
20 what your system has determined as
21 excessive, not suspicious.

22 And if they felt -- in some
23 cases that I'm aware of, they felt
24 that they were helping the Agency, but
25 you still had to discuss with them the

1 requirement of the regulation about
2 reporting suspicious orders.

3 QUESTIONS BY MR. LOESER:

4 Q. And --

5 A. But keep in mind, this was
6 accepted by the Agency from 19 -- from the
7 '70s, probably, till up until 2007.

8 Q. Right.

9 And so for the period 1998
10 through 2007, the guidance you gave to your
11 clients was that they needed to report
12 suspicious orders. However, the
13 investigation of those orders after they
14 reported them was something that the DEA did
15 and that your clients did not have to do?

16 A. Yeah.

17 MR. DAVISON: Objection. Asked
18 and answered three times.

19 THE WITNESS: No. The thing is
20 that if it's -- if an order -- if
21 yours pend and you think it's maybe
22 suspicious, do the due diligence on
23 it. And if it is suspicious, then
24 report it to the DEA.

25

1 QUESTIONS BY MR. LOESER:

2 Q. And that's what you told your
3 clients between the time period 1998
4 through 2007?

5 A. Yes.

6 Q. Is it your opinion that a
7 registrant can use any data available to it
8 to assist in determining whether an order is
9 suspicious?

10 MR. DAVISON: Objection.

11 THE WITNESS: When you say "any
12 data," there would be -- they could
13 use, you know, their own reviews that
14 they do, any on-sites, any
15 questionnaires. They could use a
16 number of processes or procedures or
17 knowledge in order to make a
18 determination that order is suspicious
19 or not suspicious.

20 QUESTIONS BY MR. LOESER:

21 Q. And you mentioned chargeback
22 data is one source of data they could use?

23 A. That -- not so much a
24 suspicious order but a -- because everything
25 is after the fact, and it was never intended.

1 But to tell you, you know,
2 there's something here that this person is
3 buying from all these distributors, and I'm
4 getting hit with multiple chargebacks, this
5 doesn't make sense. Let me tell my
6 customers, I'm not going to give you any more
7 chargebacks on this -- this registrant.

8 And I'll also -- so I sent them
9 a letter, all the distributors, and I sent a
10 letter to DEA, copied that letter telling
11 DEA, "Hey, we may have an issue here. Here's
12 the issue."

13 And DEA would do something with
14 that.

15 Q. And are you familiar with IMS
16 data?

17 A. Not really. No. Unless it's
18 prescription data or something, no, it's --
19 no, I'm not familiar.

20 Q. Is prescription data something
21 that a registrant could utilize as part of
22 its SOM program?

23 A. I --

24 MR. DAVISON: Objection.

25 THE WITNESS: I couldn't answer

1 that question. I know DEA uses it for
2 quotas, I think at one time. I don't
3 know if they still do.

4 QUESTIONS BY MR. LOESER:

5 Q. Are you familiar with IQVIA?

6 A. That's a company that -- one of
7 those companies, but I was gone before that
8 happened. So there was a whole chain of
9 companies.

10 Q. Are you familiar with the data
11 that they generate?

12 A. No.

13 Q. What about --

14 A. We had -- excuse me. We had
15 our own business unit that had many functions
16 besides Buzzeeo, but I really can't tell you
17 what they are, but it was outside the data
18 area.

19 Q. What about 852 data?

20 A. What is that?

21 Q. 852 data, do you know what that
22 is?

23 A. No.

24 Q. 867 data?

25 A. No.

1 Q. 844 data?

2 A. No.

3 Q. Are you familiar with any other
4 data sources that manufacturers or
5 distributors could utilize to help inform
6 their SOM program?

7 MR. DAVISON: Objection.

8 THE WITNESS: Possibly
9 newspaper articles could be helpful.
10 Federal Registers could be helpful.
11 If you get information from state
12 police or local police. Mallinckrodt
13 had one of those cases from Tennessee.

14 You know, there's data you
15 could look at, and depending on the
16 circumstances, you want that
17 additional data.

18 QUESTIONS BY MR. LOESER:

19 Q. In this 1998 to 2007 time
20 frame, do you know if the DEA provided any
21 guidance regarding what an excessive purchase
22 was?

23 A. The first guide came out --
24 manufactured in 2007, December 2007, and
25 that's -- and in following that, in

1 Mallinckrodt's case, they were notified by, I
2 think it was, the St. Louis office that they
3 no longer were accepting excessive order
4 reports. And that was conveyed throughout
5 the industry.

6 That's the only guidance I'm
7 aware of during that period of time.

8 Q. If you can look at
9 paragraph 87.

10 A. 87.

11 Q. Paragraph 87, you note that you
12 were unable to find any standard operating
13 procedures for Mallinckrodt's anti-diversion
14 and SOM program for the time period 1998
15 through 2007; is that right?

16 MR. DAVISON: Objection.

17 THE WITNESS: Yes.

18 QUESTIONS BY MR. LOESER:

19 Q. And did you determine based on
20 your review of Mallinckrodt materials whether
21 Mallinckrodt, in fact, had standard operating
22 procedures for anti-diversion in its SOM
23 program for this time period?

24 A. They had draft procedures.

25 Q. Did you review these

1 procedures?

2 A. Yes.

3 Q. You reviewed procedures for the
4 1998 through 2007 time --

5 A. I reviewed SOP -- SOP -- draft
6 SOPs for this period of time. And like any
7 program, especially when changes are coming
8 back -- changing guidance, new guidance is
9 coming out, it's a changing process.

10 Now, as you know, there's no
11 requirement that a DEA registrant have
12 operating procedures. FDA has -- there was
13 no requirement that DEA registrants had
14 operating procedures. There were
15 requirements under the PDMA of wholesale
16 distribution, but under DEA, no.

17 But you have to have something
18 so your employees know what you expect. So
19 in Mallinckrodt's they had draft SOPs,
20 internal documentations, training, to ensure
21 that their employees knew what the company
22 wanted.

23 Q. And so you saw drafts, but you
24 did not see any final SOPs?

25 A. There is a final -- I think it

1 was in 19 -- in 2012 or 2011. I don't
2 remember the date.

3 Q. All right. I'm asking you
4 about the 1998 through 2007 time period.

5 A. No, it was mainly drafts during
6 that period of time that I looked at.

7 Q. How many drafts did you look
8 at?

9 A. They kept changing. I don't
10 want to give a number, but there was a number
11 of them, as I recall.

12 Q. And were you able to determine
13 from those drafts what SOPs Mallinckrodt
14 actually had in place?

15 A. Well, they were draft SOPs that
16 was followed by the staff, and they kept --
17 as guidance would change, as the program
18 changed, go from excessive order to peculiar,
19 they would update the drafts. Who was
20 involved in the process, they'd update the
21 drafts till they finalized it. And I've seen
22 that on other occasions.

23 Q. Sir, if you look at
24 paragraph 89 of your report, you write, "It
25 is my opinion that 1998 through 2007,

1 Mallinckrodt's suspicious order monitoring
2 system was sufficient and effective to detect
3 and report suspicious orders to DEA."

4 Did I read that right?

5 A. Yes.

6 Q. So is it your opinion that
7 Mallinckrodt's SOM program for that time
8 period detected all suspicious orders
9 received by Mallinckrodt?

10 A. Yes.

11 Q. And reported all such orders to
12 the DEA?

13 A. They reported -- during this
14 period, they had a system in place where they
15 would report -- I think that was what, 2007?
16 Might be 2007.

17 They had -- that period of time
18 they had an excessive order report and they
19 had -- they utilized that in order to meet
20 the regulatory requirements, and that was the
21 report that was accepted by DEA and was an
22 industry standard.

23 Q. Okay. I just want to make sure
24 I understand. Your opinion is that they did,
25 in fact, identify and report all suspicious

1 orders during that time period?

2 A. That they were reporting --

3 MR. DAVISON: Objection.

4 THE WITNESS: -- excessive

5 orders during that period until the

6 DEA letter came out.

7 And, you know, it states you

8 have to report suspicious orders, and

9 this was being accepted by DEA as an

10 industry standard for a number of

11 years.

12 QUESTIONS BY MR. LOESER:

13 Q. In forming this opinion that is
14 expressed in paragraph 89, did you do any
15 evaluation of the orders received and shipped
16 by Mallinckrodt during this time period?

17 A. No, I looked at the operating
18 procedures, depositions, testimony, in order
19 to render my opinion.

20 Q. Your report indicates that "in
21 addition to having an algorithm to identify
22 suspicious orders, Mallinckrodt also had
23 additional procedures to identify suspicious
24 orders, including having customer service
25 reps and national account managers review and

1 provide input."

2 Is that right?

3 A. What paragraph are you looking
4 at?

5 Q. Paragraph 85.

6 A. Yes, they had the excessive
7 order reports in place. They utilize, as you
8 can see here, the customer service
9 representatives because they were looking at
10 all the incoming orders and the 222 forms.
11 They utilized their project managers looking
12 for -- because they were on site. They would
13 know their customers. They had been trained.

14 So it's what I said here. So
15 this was all part of their program.

16 Q. And other than what's
17 identified in paragraph 85, were there any
18 other aspects of the suspicious order program
19 that you were able to identify based on your
20 review?

21 A. In that period of time?

22 Q. Yeah.

23 A. It was mainly this.

24 Q. Was there anything else at all
25 that you identified?

1 A. Let's see. The excessive
2 order, customer sales reps, project managers,
3 compliance. That's probably as I recall, as
4 I wrote here.

5 But I didn't see -- keep in
6 mind that it was still compliance that was
7 making the final decision to ship/don't ship,
8 not the salespeople.

9 Q. And in paragraph 85 you
10 reference the algorithm that generated
11 excessive purchase reports.

12 How did that algorithm work?

13 A. Okay. They had -- they had a
14 process, algorithm, that was ■ times, then
15 they lowered it to ■, and then it's back --
16 it was back up at ■.

17 So as the process evolved and
18 they looked, you know, at the orders and they
19 had additional data in the system, that
20 algorithm would change. That number would
21 change.

22 Q. And so if you were to diagram
23 that algorithm mathematically, it would look
24 like ■ or ■ or ■

25 A. Yeah.

1 Q. There was no other calculation
2 that needed to happen?

3 A. No.

4 MR. DAVISON: Objection.

5 VIDEOGRAPHER: Off the record
6 at 4:10 p.m.

7 (Off the record at 4:10 p.m.)

8 VIDEOGRAPHER: We're back on
9 the record at 4:33 p.m.

10 QUESTIONS BY MR. LOESER:

11 Q. Mr. Buzzeeo, when we were
12 talking about paragraph 87 of your report,
13 you mentioned draft SOPs that you claim that
14 you reviewed.

15 There are no draft SOPs cited
16 in your report and -- is that right?

17 MR. DAVISON: Objection.

18 THE WITNESS: Yeah, I -- you
19 mean in my report?

20 I did under footnote 100. I
21 talked about written SOPs.

22 QUESTIONS BY MR. LOESER:

23 Q. Right.

24 But footnote 100 says, "There
25 is no statutory or regulatory requirement

1 that a company have written SOPs related to
2 suspicious order monitoring."

3 And I'm asking you, in your
4 testimony you talked about draft SOPs --

5 A. Yes.

6 Q. -- for the pre-2008 time
7 period.

8 And what I'm asking you is
9 whether you cite to those draft SOPs anywhere
10 in your report?

11 A. Oh, I see what you're saying.

12 As I recall, no.

13 Q. And are those draft SOPs listed
14 in your materials considered in Exhibit B of
15 your report?

16 A. I don't recall. There's so
17 much material in here, I'd have to go back
18 and look. I don't recall.

19 Q. And you're certain, sir, that
20 you reviewed draft SOPs from the pre-2008
21 time period?

22 A. There was draft SOPs that I
23 reviewed and -- I don't recall the dates, but
24 I think it's from that period, yes.

25 MR. LOESER: Counsel, I don't

1 believe we received any pre-2008 draft
2 SOPs, so if you could check to see if
3 those have actually been produced.

4 MR. DAVISON: Everything has
5 been produced, and everything he
6 reviewed has been listed in his
7 materials considered list.

8 MR. LOESER: Okay. Well,
9 perhaps you can identify on -- not
10 right now, but subsequently, of the
11 Bates-numbered items which ones are
12 draft SOPs.

13 MR. DAVISON: We'll take it
14 under advisement.

15 QUESTIONS BY MR. LOESER:

16 Q. Sir, could you tell me what an
17 order of interest is?

18 A. Excuse me?

19 Q. An order of interest. You
20 referred to an order of interest when we were
21 talking about suspicious orders.

22 What is an order of interest?

23 MR. DAVISON: Objection.

24 THE WITNESS: It could be the
25 excessive order or order of interest,

1 something that you should look
2 further, to make a determination it
3 may be suspicious or not.

4 But in the chargeback area, to
5 me it's just an order of interest.
6 It's not suspicious. It warrants some
7 further review if we refer to
8 chargeback data, and it's something
9 that we would refer to DEA, or it
10 would be referred to DEA to look at.

11 QUESTIONS BY MR. LOESER:

12 Q. And what are some
13 characteristics of what you would consider an
14 order of interest?

15 A. Maybe purchases from more than
16 one distributor. Maybe quantity. It could
17 be, you know, different things that really is
18 not suspicious in nature but it's -- because
19 remember, it's an after-the-fact. It's not
20 an order, it's a distribution, so it's after
21 the fact.

22 And until that financial report
23 comes in, it could be, you know, requests,
24 chargeback. It could be a month, two months,
25 three months. You know, I don't know how

1 long that could be.

2 So it's more of an order of
3 interest, so I'm sending it to DEA and, you
4 know, all the distributors that there's
5 something that you may want to look at.

6 Q. Is it appropriate to stop an
7 order than fill the order from a different
8 source?

9 MR. DAVISON: Objection.

10 QUESTIONS BY MR. LOESER:

11 Q. So if a distributor stops an
12 order, or a manufacturer stops an order from
13 a distributor and then fills the same order
14 from another source, is that appropriate?

15 MR. DAVISON: Objection.

16 THE WITNESS: I don't -- so
17 manufacturer stops an order for one of
18 their customers, stops an order for
19 one of their customers, then ships
20 from another location?

21 QUESTIONS BY MR. LOESER:

22 Q. Right.

23 A. Are we talking about
24 Mallinckrodt? Because -- okay.

25 I don't know the circumstances

1 why they stopped it. Was it because they're
2 out of stock or they made a determination it
3 was suspicious?

4 I can't answer that question.
5 I don't know all the details.

6 Q. You mentioned text messages in
7 your earlier testimony.

8 Did you review text messages --

9 A. No, I made a mistake on that.
10 I spoke out of turn.

11 I reviewed the documents here.
12 There were memos and e-mails, I meant to say.
13 And then as you see here, the list. I
14 didn't -- that was just a slip of the tongue.

15 Q. And does your son William still
16 work for BuzzeoPDMA?

17 A. He works for IQVIA. He has a
18 business unit in that company, and one of the
19 operations is the old BuzzeoPDMA company. I
20 don't know what the other ones are.

21 I can't remember the last time
22 we discussed business. Basically when we get
23 together, it's quality time.

24 Q. In paragraph 85 where you talk
25 about the involvement of the national account

1 managers and the customer service reps in
2 Mallinckrodt's suspicious order monitoring
3 program, you cite some deposition testimony.

4 And is the testimony cited all
5 of the testimony that you reviewed pertaining
6 to the involvement of NAMs and customer
7 service reps in Mallinckrodt's SOM program?

8 A. This was the data I looked at.

9 Q. Okay. Those were the
10 depositions you looked at?

11 A. Yes.

12 Q. And those were the pages that
13 you identified that related to this issue of
14 the involvement --

15 A. Yes.

16 Q. -- of national account
17 managers --

18 A. Yes.

19 Q. -- and customer service reps?

20 A. Yes.

21 I'm sorry.

22 Q. Do you know if you reviewed the
23 depositions of the national account managers?

24 A. I looked at them, so I reviewed
25 them, yes.

1 Q. Okay. And you haven't cited
2 any of their testimony here.

3 Is there a reason for that?

4 A. No, I just looked at it, and it
5 didn't really...

6 Q. And do you know if you have --
7 if you read the entirety of the transcripts
8 for the national account managers?

9 A. No. I don't recall, but I
10 doubt it. I just read excerpts of them.

11 Q. Was your son William involved
12 in any of the audits you did of SOM programs
13 for either manufacturers or distributors?

14 MR. DAVISON: Objection.

15 THE WITNESS: No.

16 His was more the business
17 aspect, running a company, building a
18 company.

19 QUESTIONS BY MR. LOESER:

20 Q. If you turn to paragraph 92 --

21 A. Excuse me, 92?

22 Q. 92.

23 -- you discuss the 2007 letter
24 from Joseph Rannazzisi and describe it as a
25 significant change in DEA's guidance with

1 respect to suspicious order monitoring.

2 Do you see that?

3 A. Yes.

4 Q. What's your understanding of
5 why the DEA, in your view, changed its
6 approach?

7 MR. DAVISON: Objection.

8 THE WITNESS: I really don't
9 know, not being with DEA. They made
10 this change. There had to be a
11 reason, but I don't know what that
12 reason is.

13 QUESTIONS BY MR. LOESER:

14 Q. You have no idea whether there
15 was a problem with diversion, for example,
16 that might have necessitated that change?

17 A. I wouldn't --

18 MR. DAVISON: Objection.

19 THE WITNESS: I wouldn't know
20 what the actual facts were behind --
21 or details behind those letters. I do
22 know it was a major change to the
23 industry.

24 QUESTIONS BY MR. LOESER:

25 Q. And did you ask anyone at DEA

1 about the change?

2 A. No.

3 Q. Did you explore in any way why
4 the DEA would be shifting its focus?

5 A. No.

6 Q. Were you curious at all about
7 that?

8 A. I was curious, but, you know,
9 inappropriate to call -- it's not appropriate
10 to call an agency and tell me -- tell me what
11 your reasoning was behind making this change.

12 Q. You didn't observe any problems
13 with controlled substances during that time
14 frame that would suggest it was necessary to
15 do something different?

16 MR. DAVISON: Objection.

17 THE WITNESS: There was a, you
18 know, diversion abuse problem down at
19 the practitioner level, so there --
20 there had to be reasons, but I don't
21 know those reasons.

22 QUESTIONS BY MR. LOESER:

23 Q. You audited all these
24 companies, distributors, manufacturers,
25 pharmacies, but you didn't observe any

1 problems with diversion?

2 MR. DAVISON: Objection.

3 THE WITNESS: As I mentioned, I
4 think this morning, I looked at -- we
5 looked at the registrants from the
6 perspective of are they meeting the
7 regulatory requirements, and if we
8 were aware of any new guides or
9 something, we would discuss it with
10 them.

11 QUESTIONS BY MR. LOESER:

12 Q. And how did this, what you're
13 calling a sea change from the DEA, impact the
14 guidance you gave your DEA registrant
15 clients?

16 MR. DAVISON: Objection.

17 THE WITNESS: Well, it was --
18 don't forget, for a number of years
19 DEA was accepting excessive order
20 reports, and now all of a sudden you
21 come out and tell the industry, we're
22 not going to accept them any longer.
23 And if we approved any systems in the
24 past, you know, we take that back, and
25 you have a responsibility to determine

1 whether an order is suspicious or not.

2 It's almost like becoming an
3 investigator, saying, now, you're
4 now the -- you're responsible for
5 that, making that determination. You
6 go out and investigate, and just tell
7 us when something's suspicious.

8 So that's the change that came
9 about.

10 QUESTIONS BY MR. LOESER:

11 Q. And so that affected the
12 guidance you gave your clients?

13 A. Not really.

14 MR. DAVISON: Objection.

15 THE WITNESS: But it affected
16 the -- what DEA was accepting from the
17 customers for that period of time.

18 QUESTIONS BY MR. LOESER:

19 Q. Did you --

20 A. Because the requirement for
21 reporting suspicious orders was always there.

22 Q. And did you spread the word
23 about this change in the DEA's approach to
24 your clients?

25 A. They spread it to us.

1 Now, we heard about it, but the
2 industry was sending us copies of the letters
3 and everything.

4 Q. Okay. Do you recall who sent
5 you copies of those letters?

6 A. Oh, God, no, I don't recall.
7 The vast majority of the industry, our
8 clients. Did you see this? Yes, we saw it.

9 Q. And when you received those
10 letters, what did you do to develop an
11 understanding of what they meant?

12 A. By, you know, looking at the
13 letters themselves, the -- what the industry
14 was interpreting, what we interpreted it to
15 mean. But, you know, it said basically we
16 don't -- you don't need to send us any more
17 excessive order reports. We're not going to
18 accept them any longer. This is a new
19 policy. And anything we said in the past,
20 forget about and just, you know, move forward
21 on it.

22 Again, you know, none of this
23 is regulatory requirements. It's not even a
24 policy. Really, it's a guidance letter.

25 So that's why I said it's a sea

1 change. A major, major impact on the
2 industry.

3 Q. If you look at paragraph 94 of
4 your report, you state, "Second, the 2007 DEA
5 letter articulated brand new guidance from
6 DEA that registrants must conduct an
7 independent analysis of suspicious orders
8 prior to completing a sale."

9 Do you see that?

10 A. Uh-huh. Yes.

11 Q. And is it your opinion that
12 prior to the DEA -- prior to 2007, the DEA
13 did not expect registrants to hold
14 potentially suspicious orders pending the
15 registrant's investigation of the order?

16 A. I lost you after the word what
17 I expect, but --

18 Q. Is it your opinion that prior
19 to 2007, the DEA did not expect registrants
20 to hold potentially suspicious orders pending
21 the registrant's investigation of the order?

22 MR. DAVISON: Objection.

23 THE WITNESS: Yeah, it was --
24 they were sending in excessive order
25 reports, but this letter clarified

1 that, hey, from now on, only send us
2 suspicious orders, what you made a
3 determination is suspicious.

4 QUESTIONS BY MR. LOESER:

5 Q. And again, I want to be very
6 clear with my question, so I'll try and ask
7 it again.

8 Prior to 2007, is it your
9 opinion that the DEA did not expect
10 registrants to hold potentially suspicious
11 orders pending the registrant's investigation
12 of the order?

13 MR. DAVISON: Objection.

14 THE WITNESS: It appears that
15 way because they accepted excessive
16 order reports, you know, up until that
17 period the letter came out. But
18 there's instances where some
19 companies, or a majority of companies,
20 are still reporting suspicious order
21 over and above this.

22 QUESTIONS BY MR. LOESER:

23 Q. And I'm asking specifically
24 about holding the order pending the
25 investigation. I just want to make sure I

1 understand what your view of the law was and
2 the requirements prior to 2007.

3 A. Yeah.

4 Q. Was it your view that the DEA
5 did not expect registrants to hold orders
6 pending their investigation of them?

7 MR. DAVISON: Objection. Asked
8 and answered yet again.

9 THE WITNESS: Based upon what
10 DEA was accepting, it appears that
11 way. But in addition, some companies
12 were going over and above this doing
13 due diligence, further due diligence,
14 and reporting suspicious orders.

15 But in meeting the regulatory
16 requirement, the industry was sending
17 these reports in, and DEA was
18 accepting them. That's -- I think
19 that's why they came out with the
20 letter, to clarify that.

21 QUESTIONS BY MR. LOESER:

22 Q. And was your guidance to your
23 clients in this time frame that they did not
24 need to hold orders that were flagged by
25 their systems pending their investigation of

1 the orders?

2 MR. DAVISON: Objection.

3 THE WITNESS: Our guidance, as
4 I mentioned earlier, it would have
5 been based upon here's the regulation,
6 here's what's expected of you. We
7 understand, we know that DEA has been
8 accepting these additional reports.

9 That would have been our
10 expression to them or our guidance to
11 them.

12 When the 2007 letter came out,
13 we said, "Hey, you know, as you read,
14 the letters we have, this thing said
15 we don't want any more excessive order
16 reports. Just make your
17 determination; ship us a suspicious
18 order."

19 QUESTIONS BY MR. LOESER:

20 Q. And again, I'm asking about
21 whether they should hold the orders pending
22 the investigation.

23 A. Okay.

24 Q. And so you've described a
25 change where, before 2007, if I understand

1 your report correctly, you believe the DEA
2 did not require registrants to hold orders
3 pending investigation.

4 But after 2007, is it your
5 opinion that the DEA started requiring
6 registrants to hold orders pending
7 investigation?

8 A. Pending -- after 2000 --

9 MR. DAVISON: Objection.

10 Go ahead.

11 THE WITNESS: The Agency --
12 basically what they're saying is, you
13 tell us only about suspicious orders,
14 and make a determination if the order
15 is suspicious.

16 Now, if they're asking me to
17 ship/don't ship, DEA said it's your --
18 if any guidance put out that DEA did,
19 was you make the determination whether
20 you ship or not ship.

21 Is that what you're asking?

22 QUESTIONS BY MR. LOESER:

23 Q. I'm just asking whether it was
24 necessary to hold the order pending the
25 investigation.

1 A. That's ship/don't ship.

2 MR. DAVISON: Objection.

3 QUESTIONS BY MR. LOESER:

4 Q. Okay. So you're saying that
5 the before 2007, DEA did not expect
6 registrants to hold the order pending
7 investigation, right?

8 A. Like I said earlier, there's no
9 regulatory requirements you hold an order.
10 Just report a suspicious order.

11 Q. So the answer to my question is
12 yes, prior to 2007, your view is the DEA did
13 not expect registrants to hold orders pending
14 investigation?

15 A. Do they even expect that now?
16 They expect you to report suspicious orders.

17 Now, if they've gone further
18 and said you're now responsible for some --
19 if there's diversion out there, so I would
20 assume then, yes, that's what they're
21 expecting now, that you're to make that
22 determination to ship/don't ship. Otherwise,
23 they're going to tie you into the
24 investigation.

25 Q. Before 2007, did you advise

1 your clients to hold orders pending their
2 investigation of them?

3 MR. DAVISON: Objection. Asked
4 and answered.

5 THE WITNESS: Depending on the
6 details, the investigation, there are
7 orders. Once it becomes suspicious,
8 the company has to make a
9 determination to ship/don't ship.

10 We would advise our clients,
11 make sure you do good due diligence on
12 whether an order is suspicious or not.

13 What I'm also saying is in that
14 period of time prior to 2011, DEA
15 accepted as part of that regulatory
16 requirement that you send -- that they
17 were sending in excessive order
18 reports and they accepted them.

19 QUESTIONS BY MR. LOESER:

20 Q. Sir, I'm just trying to figure
21 out, you've talked about a sea change in
22 2007, and you've described what you referred
23 to as a sea change in your report.

24 And what you describe is that
25 the DEA required registrants to hold orders

1 pending investigation after 2007.

2 So all I'm asking you is --

3 A. Yes.

4 Q. -- it your understanding that
5 prior to 2007, did the DEA not expect
6 registrants to hold orders pending their
7 investigation?

8 MR. DAVISON: Objection.

9 THE WITNESS: Based upon the
10 letter, DEA now expected you to hold
11 the order before you complete the
12 sale.

13 QUESTIONS BY MR. LOESER:

14 Q. Okay.

15 A. Prior to that, DEA accepted the
16 excessive order reports that may have
17 included or not included suspicious orders.

18 Q. And so before and after that
19 letter, how did your guidance change to your
20 clients with regard to whether they needed to
21 hold orders pending their investigation?

22 MR. DAVISON: Objection.

23 THE WITNESS: Our guidance
24 always was that based upon the
25 regulation, you determine if an order

1 is suspicious, and if so, don't ship
2 it. You make a determination if it's
3 suspicious or not.

4 If you make a determination
5 that it's suspicious, our guidance
6 would have been to you, you'd better
7 be very careful that this is not
8 leading to diversion, and you may want
9 to reconsider whether you ship an
10 order or not.

11 But a number of companies
12 didn't ship, or some companies didn't
13 ship.

14 I think I've clarified your
15 question.

16 QUESTIONS BY MR. LOESER:

17 Q. When you worked for the DEA,
18 did you advise registrants that they needed
19 to hold orders pending their investigation of
20 whether they were suspicious?

21 MR. DAVISON: All right. I'm
22 going to instruct you not to provide
23 any nonpublic information. So if
24 you're providing guidance to an
25 individual registrant that's not

1 public, you don't have Touhy
2 authorization from them.

3 THE WITNESS: I'm going to
4 follow the advice of my counsel.

5 QUESTIONS BY MR. LOESER:

6 Q. Was your guidance when you
7 started working for BuzzeoPDMA with regard to
8 whether to hold investigation -- hold orders
9 pending investigation different than it was
10 when you worked for the DEA?

11 MR. DAVISON: Objection.

12 THE WITNESS: I'm only going to
13 mention when we were working with the
14 industry as consultants, and services
15 we provided, that our counsel, from a
16 regulatory perspective, would be to --
17 what we felt the regulations intended
18 for the industry to do. So 1301.74(b)
19 would be, here's the regulation.
20 There's really no guidance -- there's
21 no guidance on it, there's no
22 standard. You have to make a
23 determination to report a
24 suspicious -- whether an order is
25 suspicious, and if it's suspicious,

1 report it.

2 You're then going to make a
3 determination whether to ship it or
4 not. And that's your determination,
5 but you should be careful in case
6 it's -- the product is being diverted.

7 So those are what we would say
8 to the industry.

9 QUESTIONS BY MR. LOESER:

10 Q. And so this 2007 letter from
11 Rannazzisi did not change your advice or your
12 guidance regarding whether to be careful
13 about shipping orders flagged as suspicious?

14 MR. DAVISON: Objection.

15 THE WITNESS: It would change,
16 because for now we were saying to
17 them, look, DEA -- you put out
18 excessive order reports. DEA accepted
19 it. If you didn't get the hint to the
20 letter, you better stop doing that.

21 Number two, all DEA wants you
22 to report is a suspicious order.

23 And DEA is saying to you,
24 industry, you got to make that
25 determination whether it should be

1 shipped or not, because they're very
2 clear in here that suspicious
3 orders -- they should do their review
4 prior to completing the sale.

5 That was a sea change.

6 QUESTIONS BY MR. LOESER:

7 Q. But it's always been your view
8 that orders shouldn't be shipped until the
9 investigation is complete, right?

10 MR. DAVISON: Objection.

11 THE WITNESS: You're taking a
12 chance if you ship an order that you
13 deem suspicious.

14 QUESTIONS BY MR. LOESER:

15 Q. And so your guidance has always
16 been to your clients that that's not a good
17 idea?

18 MR. DAVISON: Objection.

19 THE WITNESS: Yeah, again,
20 depending on the details, the facts,
21 things like that.

22 QUESTIONS BY MR. LOESER:

23 Q. All right. If you look at note
24 127 of your report, and this is in the 2008,
25 2009 time period, you state, "Over time, the

1 group responsible for monitoring" --

2 A. Excuse me. Which number?

3 Q. Footnote 127 on page 24.

4 A. 127.

5 MR. DAVISON: Footnote.

6 THE WITNESS: Oh, footnote.

7 Oh.

8 QUESTIONS BY MR. LOESER:

9 Q. Page 24.

10 A. Okay. Number one oh --

11 Q. 127.

12 A. Okay.

13 Q. You state, "Over time, the
14 group responsible for monitoring shifted from
15 customer service managers trained by the
16 controlled substances compliance group to
17 trade compliance and then to controlled
18 substances compliance personnel. While it
19 was not improper for a customer service
20 manager to perform the monitoring duties,
21 Mallinckrodt determined that it would be
22 better for monitoring to be conducted in
23 compliance."

24 A. Just give me a minute. Okay.

25 Q. And I take it you reviewed some

1 information that's listed on your materials
2 considered list to provide this statement?

3 A. Yes.

4 Q. And what is your understanding
5 about why Mallinckrodt determined it would be
6 better for monitoring to be conducted in
7 compliance?

8 A. Well, they were -- as the
9 program evolved and changes were continually
10 being made, it just felt that they had the
11 resources to put it in the compliance area
12 where it really -- where it belongs.

13 Q. So it was purely a resource
14 determination?

15 A. No, it's probably -- it's a
16 compliance consideration. Since they were
17 making decisions anyway, they just felt that
18 it should be moved into that area.

19 Q. Is there anything undesirable
20 about having salespeople involved in
21 compliance decisions?

22 A. No. As long as the compliance
23 people and legal are making the final
24 determinations, you want as many people
25 involved in the process. So they're part of

1 the -- have an understanding of what should
2 or shouldn't be done.

3 It's like security, you know,
4 having security involved in the process but
5 not running the program.

6 Q. And help me understand why it's
7 better then not to have those salespeople
8 involved.

9 MR. DAVISON: Objection.

10 THE WITNESS: I don't know if
11 the word is "better." It's just --
12 would decentralize the function.

13 As you gather more information,
14 as a program evolves, you begin to
15 look at -- you know, it's not the
16 function, but do we have it at the
17 right spot. It's not that these
18 people didn't do a good job, but do we
19 have it in the right spot. Where
20 should it be.

21 Companies are looking many
22 times, and I've been asked many -- the
23 question: Should we put this function
24 in legal? Should we put this function
25 in security? Should we put this

1 function in sales and management?

2 Depending on the company, you
3 put things where they would better
4 function.

5 QUESTIONS BY MR. LOESER:

6 Q. And in all of your years of
7 auditing and understanding that you've
8 developed of the industry over time, do you
9 have any thought that having salespeople
10 involved in compliance decisions is
11 undesirable because salespeople have a
12 conflict?

13 MR. DAVISON: Objection.

14 THE WITNESS: You don't want
15 anybody outside of compliance and
16 legal making the decisions. If we
17 talk about SOM, ship/don't ship,
18 that's where you want that process.

19 And then you have legal and
20 compliance working closely together
21 from a regulatory perspective, from a
22 legal perspective. Look, this is a --
23 we've made the determination it's
24 suspicious. We don't want to ship it.
25 Legal and regulatory discuss that

1 from -- like I said, from a legal and
2 regulatory.

3 It's not undesirable. You want
4 as many -- you want as many
5 operations, set of people, operations
6 involved in the program you're
7 running, especially in the compliance
8 area, so that they're aware of what's
9 responsible. They're aware of what
10 they're looking -- that the company
11 requires you to look for.

12 QUESTIONS BY MR. LOESER:

13 Q. Well, from what you've
14 described here, they reduced the number of
15 parties that were involved in the process,
16 right, because they eliminated the sales and
17 customer service people?

18 MR. DAVISON: Objection.

19 THE WITNESS: Well, they
20 were --

21 QUESTIONS BY MR. LOESER:

22 Q. Isn't that what you describe?

23 MR. DAVISON: Objection.

24 THE WITNESS: It's -- they
25 eliminate sales. They still were

1 involved in some role. If they see
2 something -- there was training
3 programs on a regular basis. Karen
4 Harper would run training programs for
5 them. But the actual processing of
6 the order, from that perspective, they
7 put into compliance.

8 QUESTIONS BY MR. LOESER:

9 Q. And can you give me any other
10 information about why what you described in
11 footnote 27 is better?

12 MR. DAVISON: Objection.

13 THE WITNESS: 127?

14 QUESTIONS BY MR. LOESER:

15 Q. Yeah, the footnote we just have
16 been reviewing.

17 A. As I say here, in order --
18 after the guidance that -- DEA guidance in
19 revising their program, that they decided
20 that, you know, this would fit better in
21 order to meet that guidance that DEA was
22 putting out. And that's what I say here.

23 Q. So it was DEA guidance that
24 caused Mallinckrodt to eliminate customer
25 service and sales personnel from the

1 compliance program?

2 MR. DAVISON: Objection.

3 THE WITNESS: I wouldn't say
4 that. I would say more or less as the
5 program evolved, they wanted to
6 centralize the program, which is
7 customary in the industry.

8 If you look back over the
9 years, you handled things a certain
10 way. Then as a program evolves, you
11 get more guidance, more programs
12 involved, more maybe technical support
13 from the company, things begin to
14 evolve, changes are made.

15 I've seen that in numerous
16 occasions. It was in security. Then
17 it's in compliance.

18 QUESTIONS BY MR. LOESER:

19 Q. So it's your opinion that sales
20 and customer service people were not removed
21 by Mallinckrodt because there was a
22 recognition that having sales and customer
23 service involved in that process was
24 undesirable?

25 MR. DAVISON: Objection.

1 QUESTIONS BY MR. LOESER:

2 Q. Was undesirable?

3 A. No. No, not based upon that at
4 all.

5 Q. Look at paragraph 112 in your
6 report.

7 At paragraph 112 you state, "It
8 is my opinion that Mallinckrodt's suspicious
9 order monitoring system was sufficient and
10 effective to detect and report suspicious
11 orders to DEA in the 2008 through 2009 time
12 period."

13 Did I read that correctly?

14 A. Yes.

15 Q. And so is it your opinion that
16 the Mallinckrodt SOM program from 2008
17 through 2009, in fact, detected all
18 suspicious orders received by Mallinckrodt?

19 A. Yes. What it was is they
20 enhanced the program. They started a new
21 designation of peculiar orders. The
22 intention was to hold orders until the
23 investigation was done. Things could --
24 begun audits of, like as I put here, Sunrise.

25 Q. And, sir, is it also your

1 opinion that in the time period of 2008
2 through 2009, Mallinckrodt reported all
3 suspicious orders to the DEA?

4 A. They put out the peculiar
5 report to DEA.

6 Q. And in that report, they
7 identified all of the suspicious orders that
8 they had received?

9 A. They identified suspicious
10 orders, and Mallinckrodt would do reviews of
11 those orders.

12 Q. And in forming this opinion,
13 did you do any evaluation of the orders
14 received and shipped by Mallinckrodt during
15 this time period?

16 A. What I looked at is the process
17 that was involved in it, the process of going
18 through excessive orders to peculiar reports
19 and how they were handled by the company.

20 Q. But you did not look at any
21 actual orders; is that correct?

22 A. No. No.

23 Q. And did you review how many
24 suspicious orders Mallinckrodt reported
25 relative to overall orders?

1 MR. DAVISON: Objection.

2 THE WITNESS: I think it
3 probably -- over a period of time, and
4 I don't recall the period of time, but
5 probably -- I don't know. They
6 probably reported somewhere around
7 ten.

8 QUESTIONS BY MR. LOESER:

9 Q. And did you evaluate the number
10 that they reported relative to the total
11 number that they shipped?

12 A. Based upon their customer base
13 they have, that doesn't surprise me at all.

14 Q. And, sir, I'm asking if you
15 actually evaluated the numbers.

16 Did you look at the ratio of
17 flagged orders to shipped orders?

18 MR. DAVISON: Objection.

19 THE WITNESS: I looked at what
20 was -- what -- based upon the customer
21 base, the drugs, that -- you know,
22 whether 10 was sufficient or not.
23 Yes, 10 was sufficient.

24 QUESTIONS BY MR. LOESER:

25 Q. So you looked at the total

1 number. You look at data that showed you the
2 total number of orders that Mallinckrodt
3 shipped?

4 MR. DAVISON: Objection.

5 THE WITNESS: No, I looked at
6 the types of clients they were dealing
7 with.

8 QUESTIONS BY MR. LOESER:

9 Q. Okay. So you didn't look at
10 any of the actual data for the orders?

11 A. I looked at the only data that
12 was -- and I don't know -- data that was
13 shipped, like, to Sunrise and what they did
14 on that.

15 But overall, just looking at
16 the program, it was my professional opinion
17 that their program met the regulatory
18 requirements.

19 Number of reports does not
20 determine whether a program is compliant or
21 not.

22 Q. Sir, if you look at
23 paragraph 117 of your report, you write that
24 "the only time that Mallinckrodt heard the
25 phrase 'know your customers' customers' from

1 DEA was in a one-off statement by a DEA
2 diversion group supervisor during a nonpublic
3 audit."

4 Do you see that?

5 A. Uh-huh.

6 Q. How do you know that was a
7 one-off statement?

8 A. Because I've never -- nobody
9 else in the industry heard it that I'm aware
10 of, and the DEA has put nothing out on that
11 during this period of time.

12 Q. And did you review all of the
13 discovery in this case to see if that
14 statement was made elsewhere?

15 A. And also there was -- Joe
16 Rannazzisi made a statement he wasn't aware
17 of "know your customer's customer" until he
18 retired. And some of the other DEA people
19 made statements to that effect also.

20 Q. And so, sir, did you review the
21 other discovery in this case, all of it, to
22 see if that -- if there's reference to
23 knowing your customer's customer elsewhere?

24 A. I looked at the data that I had
25 available to me based upon my request and

1 based upon statements I saw from DEA in some
2 of that data and the regulations. There's no
3 requirement to know your customer's customer.

4 And during the period of this
5 time as I sit here, DEA has given no further
6 guidance to the industry.

7 Q. And did you see any other
8 reference to knowing your customer's customer
9 in any of the other materials listed on your
10 materials considered list?

11 A. As I recall, I think one of the
12 plaintiffs' experts may have mentioned
13 something to that effect, and what they said
14 was is they had no idea that -- they had
15 never heard that statement before.

16 Q. So you didn't see any reference
17 to that statement in the other discovery
18 produced by Mallinckrodt in this case?

19 A. Well, just the depositions and
20 the reports I've seen.

21 Q. Okay. And so in the
22 depositions and reports, you didn't see any
23 other statements --

24 A. No.

25 Q. -- other than what you

1 mentioned?

2 A. What I mention here and
3 comments that I mentioned in here about DEA.

4 Q. And in paragraph 118, you
5 state, "I am not aware of any other DEA field
6 office making a similar statement during this
7 time period."

8 Do you see that?

9 A. Yes.

10 Q. And what did you -- what did
11 you do to investigate whether any other DEA
12 field office made similar statements during
13 this time period?

14 A. Based upon our experience,
15 based upon comments of -- would have been
16 from industry, and then also based upon what
17 Joe said and some of the others, the
18 depositions.

19 Q. All right. Anything else?

20 A. No.

21 Q. If you look at paragraph 122 of
22 your report, you state, "I have come to
23 understand that there are significant
24 limitations regarding chargeback data that
25 make it ill-suited for use in the suspicious

1 order monitoring program."

2 Did I read that accurately?

3 A. Yes.

4 Q. And footnote 155 is a reference
5 to the Buthusiem report; is that right?

6 A. Which report?

7 Q. The Buthusiem?

8 A. Yeah.

9 Q. That's what you cite for that
10 statement?

11 A. Yes.

12 Q. So is that the source of the --
13 of what you reference as your understanding
14 that there are significant limitations?

15 A. Also based upon my experience.

16 Q. And what's your experience
17 that --

18 A. Chargeback data, like I said,
19 was always a financial report over the years.
20 I wouldn't expect that anybody in the company
21 besides the financial people or maybe sales
22 and marketing would know about it.

23 It was used to -- as a --
24 depending on the service or trade, you know,
25 was it retail or was it hospital sales, and

1 that's how the program developed, from using
2 it to -- as part of an SOM program. As I
3 said, it was after the fact. And --

4 Q. Is that unusual --

5 A. -- it wasn't an order. It
6 wasn't an order, but Mallinckrodt did use it
7 in one of their investigations or reviews and
8 then, you know, is using it today also.

9 And that's what DEA said, that
10 they had to stand -- they set the standard
11 for the rest of the industry.

12 Q. Is it unusual to use
13 after-the-fact order data in a SOM program?

14 MR. DAVISON: Objection.

15 THE WITNESS: As we found here,
16 it wasn't intended for this purpose,
17 but it gave us some issues, possible
18 issues, as we said earlier, that DEA
19 may want to look at.

20 QUESTIONS BY MR. LOESER:

21 Q. In your report after
22 paragraph 122, you have -- you list A through
23 D in which you describe the limitations on
24 chargeback data.

25 Are those --

1 A. So when we're looking at A
2 through D --

3 Q. Yeah.

4 Are those items that you've
5 drawn from the Buthusiem report?

6 A. Based on?

7 Q. The expert report that you cite
8 for this.

9 A. Based upon what report?

10 Q. The Buthusiem report.

11 MR. DAVISON: Buthusiem.

12 MR. LOESER: Is that how you
13 say it?

14 MR. DAVISON: Buthusiem.

15 THE WITNESS: Oh, yes. Yes. I
16 thought it was -- he was mentioning
17 some new report or something. New
18 program.

19 Yes.

20 QUESTIONS BY MR. LOESER:

21 Q. Okay. Do you know who
22 Mr. Buthusiem is?

23 A. I don't know if I've ever asked
24 that question. I think he's former DEA.

25 Q. And prior to reading his

1 report, had you ever heard of him before?

2 A. No.

3 Q. Do you know anything about his
4 qualifications?

5 A. No.

6 Even --

7 Q. So is it your opinion that
8 chargeback data is not useful for identifying
9 suspicious orders or preventing diversion?

10 MR. DAVISON: Objection.

11 THE WITNESS: I think it's
12 sufficient for developing issues that
13 may warrant further review, but not
14 necessarily a suspicious order.

15 QUESTIONS BY MR. LOESER:

16 Q. And explain so it's clear the
17 difference between an order for which there
18 are issues requiring further review and a
19 suspicious order.

20 A. Well, I should say --

21 MR. DAVISON: Objection.

22 THE WITNESS: -- this is not an
23 order, it's an after-the-fact sale, I
24 meant to say. So a chargeback, the
25 sale has already been consummated.

1 And the company -- as I
2 mentioned earlier, it has to do with
3 the pricing, as I understand it. And
4 the company comes back and requests
5 reimbursement for the price that they
6 sold it to. So it's after-the-fact
7 sales.

8 So you may not get it, you
9 know, for some period of time. It
10 doesn't show, you know, like opioids,
11 nonopioids.

12 So Mallinckrodt's program,
13 they'll look at it. If it keys some
14 issue or something, maybe purchasing
15 from a number of distributors, maybe
16 having a lot of chargebacks with that
17 particular client -- customer, DEA's
18 made the determination -- Mallinckrodt
19 made the determination that we want to
20 tell the other distributors what's
21 happening here, and we want to tell
22 DEA. We're not telling you it's a
23 suspicious order. We're just telling
24 you it's something that you may want
25 to further review.

1 And then that's up to the DEA,
2 and that's up to the other
3 wholesalers.

4 QUESTIONS BY MR. LOESER:

5 Q. Sir, you referred to orders
6 that you described as having issues requiring
7 further review, and what I'm asking you is if
8 you could please explain to me the difference
9 between an order for which there are issues
10 requiring further review and a suspicious
11 order.

12 MR. DAVISON: Objection.

13 THE WITNESS: A suspicious
14 order is an order, so you're looking
15 at it before it's shipped.

16 A chargeback is a financial
17 report where the distribution or the
18 sale has already been made. The
19 product is out the door. It's already
20 been made. It's a financial -- it was
21 intended only as a financial report
22 based upon the level of trade.

23 So for pharmacy -- you're
24 shipping to a pharmacy. And this
25 pharmacy supplying a hospital? Is the

1 pharmacy supplying -- and I'm just
2 using this as an example -- patients?

3 Well, for the patients you may
4 have one price; for the hospitals you
5 may have another price. This price,
6 the hospital price, may be lower. So
7 the wholesaler is losing money on that
8 sale, so they're asking the
9 manufacturer to reimburse them for
10 this.

11 So that -- as you -- as that
12 stuff accumulates -- and that's why in
13 the past nobody even understood what
14 the data was -- should be used from
15 either legal or security, from a
16 compliance perspective, for the
17 Controlled Substances Act.

18 So it's always after the fact.
19 That's why I use the word "issues"
20 instead of "suspicious." Because is
21 it really suspicious when I don't --
22 haven't really looked at it?

23 All I know is that one example
24 would be this pharmacy is buying from
25 multiple distributors.

1 Well, the question is why.

2 Well, there could be a lot of reasons.

3 Therefore, it's after.

4 I'm going to tell my
5 wholesalers, no more chargebacks for
6 them. I'm not going to reimburse you
7 anything, and I'm reporting it to DEA.

8 QUESTIONS BY MR. LOESER:

9 Q. So, sir, are you saying that a
10 manufacturer can't determine if an order is
11 suspicious with after-the-fact data?

12 MR. DAVISON: Objection.

13 THE WITNESS: Well, you keep
14 talking on orders, suspicious orders.

15 If you want to talk about
16 orders, that would be what the
17 suspicious order monitoring program --

18 QUESTIONS BY MR. LOESER:

19 Q. So when you use the phrase
20 "issues," you're never referring to an order
21 that hasn't already been shipped?

22 A. I'm referring -- in this case
23 I'm referring to chargeback distributions.

24 Q. Okay.

25 A. Or chargebacks -- financial

1 reimbursements. That's what I'm referring
2 to.

3 Q. If you look at paragraph 136 in
4 your report, you state, "It is my opinion
5 that Mallinckrodt's suspicious order
6 monitoring program was sufficient and
7 effective to detect and report suspicious
8 orders to DEA in the 2010 through 2011 time
9 period."

10 Did I read that correctly?

11 A. Yes. Yes.

12 Q. So is it your opinion that in
13 this time period Mallinckrodt, in fact,
14 detected all suspicious orders that it
15 received?

16 A. It's my opinion that
17 Mallinckrodt was reporting suspicious orders
18 to DEA.

19 Q. And again, my question was
20 simply whether your opinion is that in this
21 2010 through 2011 time period, that
22 Mallinckrodt detected all suspicious orders
23 that it received.

24 A. And my comment is Mallinckrodt
25 has reported suspicious orders to DEA.

1 Q. Maybe my question isn't clear,
2 so I'll try again.

3 Is it your opinion that in the
4 2010 through 2011 time period, Mallinckrodt
5 detected all of the suspicious orders that it
6 received?

7 A. And I'm stating that DEA {sic}
8 met the regulatory requirement and were
9 reporting suspicious orders to DEA.

10 Q. Were there orders that were
11 suspicious that Mallinckrodt did not detect?

12 A. I have no idea.

13 Q. So do you have any --

14 A. They -- and I would think the
15 company would have -- the companies, based
16 upon their systems in place, reporting
17 suspicious orders.

18 It's like any company. If you
19 have a good system, they report suspicious
20 orders.

21 Q. Well, what your opinion says
22 right here in this paragraph --

23 A. Uh-huh.

24 Q. -- is "the system was
25 sufficient and effective to detect and report

1 suspicious orders."

2 And what I'm asking you, is it
3 your opinion that Mallinckrodt, in fact,
4 detected all of the suspicious orders that it
5 received in that time period?

6 A. And this is my opinion.

7 Q. So the answer is yes?

8 A. This is my opinion. DEA --
9 whatever -- exactly what I said here.
10 "Mallinckrodt" -- my opinion.
11 "Mallinckrodt's suspicious order monitoring
12 system was sufficient and effective to detect
13 and report suspicious orders to DEA in the
14 2010-2011 time period."

15 That's my opinion.

16 Q. And I'm asking you a question
17 based on that opinion.

18 And that question is: Is it
19 your opinion that Mallinckrodt, in fact,
20 detected all suspicious orders that it
21 received?

22 MR. DAVISON: Objection.

23 Argumentative. You've asked it about
24 four times now. Getting into
25 harassment here, Derek.

1 THE WITNESS: It's my opinion,
2 as I stated to you, that
3 Mallinckrodt's system reported
4 suspicious orders to DEA in this time
5 frame.

6 QUESTIONS BY MR. LOESER:

7 Q. So you don't have an opinion on
8 whether Mallinckrodt, in fact, detected all
9 the suspicious orders it received?

10 A. I do have an opinion.

11 MR. DAVISON: Objection.

12 THE WITNESS: I do have an
13 opinion. And that's my opinion.

14 QUESTIONS BY MR. LOESER:

15 Q. I'm not asking you about
16 whether there was a system that existed to
17 detect the orders. I'm asking you if, in
18 fact, the system detected the orders.

19 A. And I made a factual
20 statement --

21 MR. DAVISON: Objection.

22 THE WITNESS: -- that
23 Mallinckrodt reported suspicious
24 orders.
25

1 QUESTIONS BY MR. LOESER:

2 Q. Did Mallinckrodt report all of
3 the suspicious orders that it received in
4 this time period?

5 MR. DAVISON: Objection.

6 THE WITNESS: Mallinckrodt has
7 a program in place that allows them to
8 report suspicious orders. I wrote
9 here: "It is my opinion that
10 Mallinckrodt's suspicious order
11 monitoring system was sufficient and
12 effective to detect and report
13 suspicious orders to DEA in the
14 2010-2011 time period."

15 QUESTIONS BY MR. LOESER:

16 Q. And does that mean that they,
17 in fact, reported all the suspicious orders
18 they received?

19 MR. DAVISON: Objection.

20 QUESTIONS BY MR. LOESER:

21 Q. I know they had a system, but
22 does that mean that they, in fact, detected
23 the orders and reported them? That's all I'm
24 asking you.

25 A. And what I'm telling you is

1 they had a system in place, and they reported
2 suspicious orders.

3 Q. And the system was effective.
4 Does that mean that it reported all of the
5 suspicious orders?

6 A. It means they reported --

7 MR. DAVISON: Objection.

8 Go ahead.

9 THE WITNESS: It means they
10 reported suspicious orders.

11 QUESTIONS BY MR. LOESER:

12 Q. So maybe they reported some
13 suspicious orders?

14 A. I didn't say that. You said
15 that.

16 MR. DAVISON: Objection.

17 QUESTIONS BY MR. LOESER:

18 Q. Well, is that your opinion?

19 A. My opinion is they reported
20 suspicious orders.

21 Q. So you don't know whether they
22 reported some or all of the orders?

23 MR. DAVISON: Objection.

24 THE WITNESS: I do know, based
25 upon what I said here. I don't know

1 what else to say. They reported
2 suspicious orders.

3 QUESTIONS BY MR. LOESER:

4 Q. It seems like a simple
5 question. Did they report all of them or
6 some of them?

7 MR. DAVISON: Objection. He's
8 answered your question.

9 THE WITNESS: It is my opinion
10 that Mallinckrodt's suspicious order
11 monitoring system was sufficient and
12 effective, sufficient and effective,
13 to detect and report suspicious orders
14 to the DEA in the 2010-2011 time
15 period.

16 QUESTIONS BY MR. LOESER:

17 Q. In forming this opinion, did
18 you evaluate the orders received and shipped
19 by Mallinckrodt during this time period?

20 A. I evaluated the documents that
21 you're aware of, the depositions, the
22 operating procedures I looked at, reports I
23 looked at, and I came to my decision that
24 Mallinckrodt's program met the regulatory
25 requirements.

1 Q. And so, sir, you did not review
2 the actual orders that Mallinckrodt received
3 in this time period; is that correct?

4 A. No, I did -- not the orders. I
5 looked at the process.

6 Q. And, sir, if you look at
7 paragraph 147 of your report, you state, "It
8 is my opinion that Mallinckrodt's suspicious
9 order monitoring system was sufficient and
10 effective to detect and report suspicious
11 orders to DEA from 2012 through 2018."

12 A. Correct.

13 Q. So are you saying, sir, that
14 Mallinckrodt reported all the suspicious
15 orders that it received in that time period?

16 A. Mallinckrodt's suspicious order
17 monitoring system was sufficient to detect --
18 was effective to detect and report suspicious
19 orders. They reported the suspicious orders
20 that they identified.

21 Q. Did they report all of the
22 orders?

23 MR. DAVISON: Objection.

24 THE WITNESS: They reported
25 every suspicious order.

1 QUESTIONS BY MR. LOESER:

2 Q. Okay. And how do you define
3 sufficient?

4 A. Based upon my evaluation, the
5 program was able to detect and report
6 excessive orders.

7 Q. And how do you define
8 effective?

9 A. That they were reporting
10 suspicious orders.

11 Q. And in forming this opinion for
12 the 2012 through 2018 time period, did you
13 review any of the orders that Mallinckrodt
14 actually received and shipped?

15 A. When you're looking at the
16 process and the material, you don't have to
17 actually look at orders. Because looking at
18 an individual order or a thousand orders or
19 something is not really going to tell you
20 whether something is suspicious or not.

21 So you're looking at the
22 process. You have the process in place to
23 look at the orders to make a determination.

24 That's what I looked at. I
25 looked at the regulation. I looked at the

1 guidance letters, industry experience, my
2 experience, to make that determination.

3 Q. If you could turn to
4 paragraph 153 of your report.

5 A. 153, yes.

6 Q. This is your opinion with
7 regard to the McCann and Keller
8 methodologies.

9 Do you see that?

10 A. Yes.

11 Q. And why don't you take a
12 second -- or a minute to review that, and
13 I'll ask you a few questions about that
14 paragraph.

15 A. Yes.

16 Q. Have you had a chance to review
17 that paragraph?

18 A. Yes. Yes. Thank you.

19 Q. In paragraph 153, you claim
20 that the five methodologies utilized by
21 McCann and Keller are pulled from
22 Mr. Rafalski's expert report, and no reason
23 is given as to why any of these methodologies
24 would be appropriate for any particular
25 defendant; is that right?

1 A. Correct.

2 Q. And you've reviewed each of
3 these methodologies in detail?

4 A. I reviewed the reports.

5 Q. And your testimony is that
6 Mr. Rafalski does not identify why it would
7 be appropriate to utilize any of these
8 methodologies?

9 A. Correct.

10 Q. You also state in paragraph 154
11 that Mr. Rafalski, without any analysis,
12 simply adopts the analyses of both Dr. McCann
13 and Ms. Keller and contends that each of the
14 flagged orders is, in fact, suspicious; is
15 that correct?

16 A. Where are you? Let me read
17 154.

18 Q. Okay.

19 A. Okay.

20 MR. LOESER: So could you read
21 the question back, please?

22 (Court Reporter read back
23 question.)

24 THE WITNESS: You want me to
25 respond to her question or...

1 QUESTIONS BY MR. LOESER:

2 Q. Her question is my question.

3 A. Okay. Yeah. I'm saying -- I
4 was waiting if you were going to say anything
5 else.

6 Yes, what I state here.

7 Q. And you've read the Rafalski
8 report?

9 A. Yes.

10 Q. Did you read the entire report?

11 A. Yes.

12 Q. And you read the entire McCann
13 report?

14 A. Yes.

15 Q. And you read the entire Keller
16 report?

17 A. Yes.

18 Q. And you specifically --
19 according to the footnotes here, you
20 specifically reviewed certain portions of the
21 Rafalski report which you identify as -- in
22 footnotes 199 and 200; is that correct?

23 MR. DAVISON: Objection.

24 THE WITNESS: Yeah, I read the
25 Rafalski report.

1 QUESTIONS BY MR. LOESER:

2 Q. Okay. And so the references to
3 page 40 and 41, what are you saying, that you
4 in fact read the entire report?

5 A. I -- that report I read.

6 Q. And is your opinion about the
7 Rafalski report based upon pages 40 and 41 of
8 his report?

9 MR. DAVISON: Objection.

10 THE WITNESS: Yes.

11 QUESTIONS BY MR. LOESER:

12 Q. Okay. Is it based on any other
13 part of his report?

14 A. I looked at the rest of the
15 report. I don't recall now whether I used
16 some of that or not, but I did read the
17 entire report. And out of that, I pulled out
18 what I thought was important.

19 Q. And you also cite portions of
20 the Keller report and the McCann report; is
21 that correct?

22 A. Yes.

23 Q. And you provide particular page
24 citations for the portions that support your
25 opinion?

1 A. Yes.

2 Q. And are you aware of whether
3 other portions of those reports support your
4 opinion?

5 A. This is what I looked at.
6 These are the -- that I pulled out of it,
7 that I got out of the reports that I thought
8 was important for what I was tasked to do.

9 Q. Okay. So you cited in this
10 section all of the portions of those reports
11 that you believe were relevant to your
12 opinion?

13 A. To what I was saying here, but
14 I did read the entire reports.

15 Q. And you didn't review David
16 Cutler's report; is that right?

17 A. I'd have to go back here. Did
18 I look at it or not?

19 I don't recall. I'll have to
20 go back here and look. There's so many
21 documents.

22 Q. We can make this shorter. As
23 we went through before, if a report is not
24 listed on the expert reports in your
25 materials considered --

1 A. It's not listed?

2 Q. If it's not listed, you didn't
3 review the report?

4 A. I didn't review it, no. No,
5 sir.

6 Q. And if deposition transcripts
7 are not listed in the materials considered,
8 then you didn't review those depositions?

9 A. I've only reviewed what's
10 mentioned in here.

11 Q. And, sir, you're not offering
12 any opinion on what orders received by
13 Mallinckrodt were suspicious, are you?

14 A. No, I'm just looking at the --
15 evaluating through what I read whether the
16 program was -- met the regulatory
17 requirements.

18 Q. And you haven't conducted any
19 independent analysis of what orders should
20 not have been shipped by Mallinckrodt?

21 A. No.

22 Q. And you're not doing that for
23 any other defendant either?

24 A. No. I'm not involved with any
25 other defendant in this case.

1 Q. And did you review the due
2 diligence files that Mallinckrodt maintained
3 for any of the orders that were flagged as
4 suspicious?

5 A. I reviewed the files that I
6 mentioned in my report.

7 Q. And no others?

8 A. No others.

9 Q. Sir, have you spoken to any of
10 the other experts for the defendants in this
11 case?

12 A. No.

13 Q. Is it your intention to appear
14 at trial in October in this case?

15 A. Yes, it's my intention.

16 Q. Have you requested any
17 information that you have not received from
18 Mallinckrodt's counsel?

19 A. Anything I requested, I've
20 received.

21 Q. And do you intend to conduct
22 any further research to support your
23 opinions?

24 A. I don't know at this point.

25 Q. Has something happened today

1 which would cause you to think you need to do
2 some further research?

3 A. Not at this moment, no.

4 Q. Have you prepared any
5 demonstrative exhibits that you intend to use
6 at trial?

7 A. Not -- I don't know at this
8 point in time.

9 Q. And if called by defendants
10 other than Mallinckrodt to come to trial to
11 testify about your prior consulting work for
12 the defendants, would you attend the trial
13 for that purpose?

14 A. No.

15 MR. DAVISON: Objection.

16 THE WITNESS: I think -- I
17 don't know if there'd be a conflict or
18 even a perceived conflict which would
19 be -- no, my client is Ropes & Gray --
20 Mallinckrodt through Ropes & Gray.

21 QUESTIONS BY MR. LOESER:

22 Q. And if plaintiffs called you as
23 a witness to testify about your other audits,
24 would you appear at trial and testify
25 regarding those audits?

1 MR. DAVISON: Objection.

2 THE WITNESS: For plaintiffs?

3 No.

4 QUESTIONS BY MR. LOESER:

5 Q. You would not?

6 A. No.

7 Q. Why not?

8 A. Why would I?

9 MR. DAVISON: Objection.

10 THE WITNESS: For the
11 plaintiffs?

12 I can't ride both horses.

13 QUESTIONS BY MR. LOESER:

14 Q. Now, sir, the analysis you
15 performed on Mallinckrodt's SOM program is
16 the same analysis you use when you perform
17 audits of DEA registrants, correct?

18 A. Again, it depends on the
19 circumstances, depends on what the company --
20 the customer is asking us to do, you know,
21 whether they want one thing, focused on one
22 thing or they want the entire program looked
23 at. So it really depends on the client.

24 Q. Sure.

25 And but when you're asked --

1 the approach you took to evaluating
2 Mallinckrodt's SOM approach is the same
3 approach, as you indicate in your report,
4 when evaluating other DEA registrants' SOM
5 programs; is that right?

6 A. What I used, the process I used
7 here, if that's what a company was looking
8 for, that's the way I would review it --

9 Q. And you've --

10 A. -- evaluate it.

11 Q. And you've been performing
12 these audits for DEA registrants' SOM
13 programs for over 30 years; is that right?

14 A. 2000. 1990. Yeah. Yeah,
15 close to 30 years. Wow.

16 Q. And notwithstanding performing
17 countless audits over a more than that
18 30-year time period, you have no recollection
19 at all of who you audited in this time
20 period?

21 MR. DAVISON: Objection.

22 THE WITNESS: 53 years is a
23 long time, and to remember everything
24 that you've done, it's like looking --
25 if I looked at something today and I

1 did it 10, 20, 30, years ago, I'd say,
2 what are the details behind this.
3 It's difficult.

4 All I know is we reviewed a
5 number of companies -- a number of
6 registrants, I should say, throughout
7 the distribution chain.

8 QUESTIONS BY MR. LOESER:

9 Q. And you have no recollection of
10 the specific results of any of the audits
11 you've done for other DEA registrants?

12 A. I would probably remember some
13 of the companies. A lot -- some of them
14 aren't in business any longer, through
15 acquisitions. But actual reports and
16 everything? I know there were reports, but
17 actually the details behind it or review it
18 or whatever, that would be difficult.

19 Q. And you have no ability to
20 identify whether any of the defendants in
21 this case previously were clients of yours?

22 A. We had a very large client
23 base. We touched a lot of companies out -- a
24 lot of DEA registrants out there, so there
25 could be some defendants here that we did

1 work for.

2 Q. Can you identify who they are?

3 THE WITNESS: Is there a
4 confidentiality --

5 MR. DAVISON: You can answer
6 with respect to if they're defendants
7 that you recall in this litigation.

8 THE WITNESS: So I can name
9 them?

10 MR. DAVISON: If you recall and
11 they're defendants in this litigation,
12 you can name clients, if you remember.

13 THE WITNESS: Even though I
14 have -- I don't know if we should step
15 out. Even though I have a
16 confidentiality agreement with --

17 MR. DAVISON: It's been ordered
18 you can name the companies that are
19 defendants in this litigation, if you
20 recall.

21 THE WITNESS: Even it says if
22 we can't talk about it?

23 MR. DAVISON: Can we take a
24 quick break?

25 VIDEOGRAPHER: Off the record

1 at 5:33 p.m.

2 (Off the record at 5:33 p.m.)

3 VIDEOGRAPHER: We're back on
4 the record at 5:41 p.m.

5 QUESTIONS BY MR. LOESER:

6 Q. Mr. Buzzeo, we took a break for
7 you to confer with your counsel.

8 Are you now going to answer the
9 question and identify the companies?

10 A. If I may.

11 As you know, over the years
12 I've worked for -- either myself or the
13 company, I've worked for a lot of clients.
14 And in that period of time we always had a
15 confidentiality agreement with those
16 companies.

17 Now, I know the judge has
18 ruled, I believe -- I don't understand the
19 whole thing -- that certain documents could
20 be released by the companies to the
21 attorneys.

22 Since I have these personal
23 agreements, unless the company -- I think to
24 protect myself, that the companies would have
25 to say, yep, you can answer the question,

1 identify them. Because there are companies
2 in this process that were clients of ours
3 either currently or in the past. I shouldn't
4 say "currently" because I don't know -- or in
5 the past.

6 Unless you have -- if you have
7 reports that you want me to look at that may
8 have been made available from the companies,
9 that's a different issue. Otherwise, I want
10 the blessing of each individual company.

11 Q. And, sir, are you going to ask
12 each company for permission to identify that
13 you provided an audit to them?

14 A. I guess through counsel.

15 Q. You intend to do that?

16 A. I don't intend it unless I have
17 to. It's -- but I would want to, you know,
18 say, yep, Ron, you can go ahead and do that.

19 Q. And that's --

20 A. Or at least -- the question
21 was, would I identify the companies.

22 And to identify them, I want
23 their blessing.

24 Q. And so, sir, even if those
25 companies have produced in this case the

1 audit reports that you created for them, you
2 still would not be willing to identify them
3 for purposes of this deposition?

4 MR. DAVISON: Objection.

5 THE WITNESS: I would -- if
6 companies have made available, then --
7 you want to show me something, I'd
8 look at it. I'm not guaranteeing I'd
9 remember the details behind it because
10 there's so many of them -- companies
11 that we work with and I work for.

12 But even to mention their
13 names, either as existing or past
14 clients, I want some waiver of the
15 confidentiality agreements that I have
16 with those companies.

17 QUESTIONS BY MR. LOESER:

18 Q. And, sir, why is it so
19 important to you not to reveal which
20 companies you worked for in evaluating their
21 SOM programs?

22 MR. DAVISON: Objection. Asked
23 and answered.

24 THE WITNESS: Because of the
25 confidentiality agreements either I

1 have or the company has.

2 QUESTIONS BY MR. LOESER:

3 Q. And do you have copies of those
4 confidentiality agreements?

5 A. No, I don't have any records
6 anymore.

7 Q. And so do you know for a fact
8 whether you have confidentiality agreements
9 with all of the companies that you audited?

10 A. I had confidentiality
11 agreements with everybody I worked with.

12 MR. LOESER: So for counsel
13 involved in this who represent
14 entities for which Mr. Buzzeo has
15 provided audits, we'd request that the
16 confidentiality agreements be
17 produced.

18 QUESTIONS BY MR. LOESER:

19 Q. So, sir, if I provided you with
20 a list of the defendants in this case, your
21 decision here today is that you would not
22 identify on that list which of the defendants
23 or companies for which you've provided SOM
24 program audits or evaluations?

25 A. I feel that I'm bound by the

1 confidentiality agreements and the work I
2 did for those -- with those possible
3 companies.

4 Q. Mr. Buzzeo, could you please
5 tell the jury whether you have any actual or
6 potential conflicts of interest that prevent
7 you from providing an impartial opinion in
8 this case with regard to whether DEA
9 registrants engaged in conduct that violated
10 the CSA and its implementing regulations?

11 A. You mean the jury?

12 Q. I guess I'm just -- this
13 deposition is for the purpose of the trial,
14 case.

15 A. Oh, okay. I was wondering
16 where the jury came in.

17 Q. The jury will be reviewing your
18 testimony.

19 A. That I was aware of. That I
20 was aware of.

21 Q. So could you please tell the
22 jury whether you have any actual or potential
23 conflicts of interest that prevent you from
24 providing an impartial opinion in this case
25 with regard to whether any of the defendants

1 engaged in conduct that violated the CSA and
2 its implementing regulations?

3 A. I don't believe I did.

4 MR. LOESER: We can go off the
5 record.

6 VIDEOGRAPHER: Off the record
7 at 5:46 p.m.

8 (Off the record at 5:46 p.m.)

9 VIDEOGRAPHER: We're back on
10 the record at 5:56 p.m.

11 MR. LOESER: I have no further
12 questions at this time.

13 MR. DAVISON: I just have a
14 brief redirect.

15 EXAMINATION

16 QUESTIONS BY MR. DAVISON:

17 Q. Mr. Buzzeeo, do you recall
18 testifying earlier today about reviewing
19 draft SOPs from prior to 2008?

20 A. Yes, I do.

21 Q. Is there anything you'd like to
22 say about the testimony?

23 A. Yes. I misspoke, and it was
24 actually from 2008 forward, not prior to
25 2008.

1 MR. DAVISON: Thank you. I
2 have nothing further.

3 VIDEOGRAPHER: Okay. This
4 concludes today's deposition. The
5 time is 5:57 p.m. We're off the
6 record.

7 (Deposition concluded at 5:57 p.m.)

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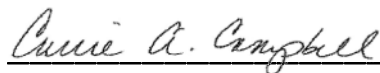
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CERTIFICATE

I, CARRIE A. CAMPBELL, Registered
Diplomate Reporter, Certified Realtime
Reporter and Certified Shorthand Reporter, do
hereby certify that prior to the commencement
of the examination, Ronald Buzzeo, was duly
sworn by me to testify to the truth, the
whole truth and nothing but the truth.

I DO FURTHER CERTIFY that the
foregoing is a verbatim transcript of the
testimony as taken stenographically by and
before me at the time, place and on the date
hereinbefore set forth, to the best of my
ability.

I DO FURTHER CERTIFY that I am
neither a relative nor employee nor attorney
nor counsel of any of the parties to this
action, and that I am neither a relative nor
employee of such attorney or counsel, and
that I am not financially interested in the
action.



CARRIE A. CAMPBELL,
NCRA Registered Diplomate Reporter
Certified Realtime Reporter
Notary Public
Dated: July 1, 2019

1 INSTRUCTIONS TO WITNESS

2
3 Please read your deposition over
4 carefully and make any necessary corrections.
5 You should state the reason in the
6 appropriate space on the errata sheet for any
7 corrections that are made.

8 After doing so, please sign the
9 errata sheet and date it. You are signing
10 same subject to the changes you have noted on
11 the errata sheet, which will be attached to
12 your deposition.

13 It is imperative that you return
14 the original errata sheet to the deposing
15 attorney within thirty (30) days of receipt
16 of the deposition transcript by you. If you
17 fail to do so, the deposition transcript may
18 be deemed to be accurate and may be used in
19 court.

1 ACKNOWLEDGMENT OF DEPONENT

2
3
4 I, _____, do
hereby certify that I have read the foregoing
5 pages and that the same is a correct
transcription of the answers given by me to
6 the questions therein propounded, except for
the corrections or changes in form or
7 substance, if any, noted in the attached
Errata Sheet.

8
9
10
11
12 _____
Ronald W. Buzzeo, R.Ph.

DATE

13
14
15 Subscribed and sworn to before me this
16 _____ day of _____, 20 ____.

17 My commission expires: _____
18

19 Notary Public
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ERRATA

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